

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

MDL NO. 2804

CASE NO. 17-md-2804

Hon. Dan A. Polster

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

TRACK THREE CASES

REMOTE VIDEO DEPOSITION OF KATHERINE KEYES, PH.D.

June 3, 2021

REPORTED BY: Laura H. Nichols
Certified Realtime Reporter,
Registered Professional
Reporter and Notary Public

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A P P E A R A N C E S

(All Appearing Remotely)

FOR THE PLAINTIFFS:

Messrs. Donald C. Arbitblit
Ian Bensberg, Britt Cibulka
and Matias Bustamante

Attorneys at Law

Lieff Cabraser Heimann & Bernstein, LLP
275 Battery Street, 29th Floor
San Francisco, California 94111-3339
(415) 956-1000
darbitblit@lchb.com
ibensberg@lchb.com
mbustamante@lchb.com
bcibulka@lchb.com

-and-

Ms. Paulina do Amaral
Attorney at Law

Lieff Cabraser Heimann & Bernstein, LLP
250 Hudson Street
Eighth Floor
New York, New York 10013
(212) 355.9500
pdoamaral@lchb.com

1 A P P E A R A N C E S (Continuing)

2 (All Appearing Remotely)

3
4 ALSO FOR THE PLAINTIFFS:

5 Mr. Peter H. Weinberger

6 Attorney at Law

7 Spangenberg Shibley & Liber LLP

8 1001 Lakeside Avenue East

9 Suite 1700

10 Cleveland, Ohio 44114

11 (216) 600-0114

12 pweinberger@spanglaw.com

13
14 ALSO FOR THE PLAINTIFFS:

15 Ms. Jo Anna Pollock

16 Attorney at Law

17 Simmons Hanly Conroy

18 One Court Street

19 Alton, Illinois 62002

20 jpollock@simmonsfirm.com

21 (618) 693-3104

A P P E A R A N C E S (Continuing)

(All Appearing Remotely)

FOR THE DEFENDANT, RITE AID:

Ms. Elizabeth I. Buechner

Attorney at Law

Morgan, Lewis & Bockius LLP

101 Park Avenue

New York, New York 10178-0060

(212) 309-6000

elizabeth.buechner@morganlewis.com

FOR THE DEFENDANT, WALGREENS BOOTS ALLIANCE, INC.;

WALGREEN CO.; AND WALGREEN EASTERN CO., INC.:

Mr. Kaspar Stoffelmayr

Attorney at Law

Bartlit Beck

Courthouse Place

54 West Hubbard Street

Chicago, Illinois 60654

(312) 494-4400

kaspar.stoffelmayr@bartlitbeck.com

A P P E A R A N C E S (Continuing)

(All Appearing Remotely)

FOR THE DEFENDANT, WALMART, INC.:

Mr. Edward M. Carter

Attorney at Law

Jones Day

325 John H. McConnell Boulevard

Suite 600

Columbus, Ohio

(614) 281-3838

emcarter@jonesday.com

FOR DEFENDANTS CVS PHARMACY, INC.; CVS INDIANA,
LLC; CVS RX SERVICES, INC.; CVS TN DISTRIBUTION,
LLC and OHIO CVS STORES, LLC:

Messrs. Steven N. Herman and Jason B. Acton

Attorneys at Law

Zuckerman Spaeder

1800 M Street Northwest

Suite 1000

Washington, DC 20036-5807

(202) 778-1800

sherman@zuckerman.com

jacton@zuckerman.com

A P P E A R A N C E S (Continuing)

(All Appearing Remotely)

FOR THE DEFENDANTS GIANT EAGLE, INC. and HBC
SERVICE COMPANY:

Ms. Erin Gibson Allen

Attorney at Law

Marcus & Shapira LLP

One Oxford Centre

35th Floor

Pittsburgh, Pennsylvania 15219

(412) 471-3490

allen@marcus-shapira.com

OTHERS PRESENT:

Mr. David R. Cohen

Special Master

David R. Cohen Co. LPA

24400 Chagrin Boulevard, Suite 300

Cleveland, Ohio 44122

(216) 831-0001

david@specialmaster.law

Mr. Stephen Kent, Videographer

Veritext Legal Solutions

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S T I P U L A T I O N

IT IS STIPULATED AND AGREED, by and between the parties, through their respective counsel, that the deposition of KATHERINE KEYES, PH.D. may be taken before Laura H. Nichols, Commissioner, Certified Realtime Reporter, Registered Professional Reporter and Notary Public;

That it shall not be necessary for any objections to be made by counsel to any questions, except as to form or leading questions, and that counsel for the parties may make objections and assign grounds at the time of trial, or at the time said deposition is offered in evidence, or prior thereto.

1 I, Laura H. Nichols, a Certified
2 Realtime Reporter and Registered Professional
3 Reporter of Birmingham, Alabama, and a Notary
4 Public for the State of Alabama at Large, acting as
5 Commissioner, certify that on this date, as
6 provided by the Federal Rules of Civil Procedure of
7 the United States District Court, and the foregoing
8 stipulation of counsel, there came before me
9 remotely via Zoom, on June 3, 2021, commencing at
10 11:09 a.m. EDT, KATHERINE KEYES, PH.D., witness in
11 the above cause, for oral examination, whereupon
12 the following proceedings were had:

13
14 * * *

15 THE VIDEOGRAPHER: Good morning. We
16 are going on the record at 11:09 a.m., EST, on June
17 3rd, 2021.

18 When you are not speaking, please
19 mute your audio input as your microphone is
20 sensitive and can pick up whispering and background
21 noise. Please turn off all cell phones or place
22 them away from your computer as they can interfere
23 with the deposition audio. Audio and video
24 recording will continue to take place unless all
25 parties agree to go off the record.

1 This is Media Unit 1 of the
2 video-recorded deposition of Dr. Katherine Keyes,
3 taken by counsel for defendant in the matter of In
4 Re: National Prescription Opiate Litigation Track
5 3 Cases, filed in the United States District Court
6 for the Northern District of Ohio, Eastern
7 Division. Case Number 17-MD-804.

8 This deposition is being held via
9 videoconference with the witness located in New
10 York. My name is Stephen Kent from the firm
11 Veritext Legal Solutions, and I am the
12 videographer. The court reporter is Laura Nichols,
13 also from Veritext Legal Solutions.

14 I am not authorized to administer an
15 oath. I am not related to any party in this
16 action, nor am I financially interested in the
17 outcome. All appearances will be noted on the
18 stenographic record.

19 Will the court reporter please swear
20 in the witness.

21
22 KATHERINE KEYES, PH.D.,
23 having been first duly sworn, was examined and
24 testified as follows:
25

1 EXAMINATION BY MR. HERMAN:

2 Q. Dr. Keyes, we have met before. I am
3 Steve Herman. I represent CVS. It is nice to see
4 you again.

5 Before we went on the record, we
6 talked a little bit. You received two boxes of
7 exhibits from us, correct?

8 A. Correct.

9 Q. And the one that has a sealed
10 envelope is -- my understanding, is right next to
11 you; is that correct?

12 A. Yes.

13 Q. Okay. Great. And have those
14 envelopes remained sealed?

15 A. Yes.

16 Q. Okay. Thank you. And you understand
17 that CVS is a chain pharmacy, correct?

18 A. Yes.

19 Q. And do you understand that Walmart,
20 Walgreens, Rite Aid and Giant Eagle are also chain
21 pharmacies?

22 A. Yes.

23 Q. If I refer to a group, the chain
24 pharmacies today, will you understand that to mean
25 that I am referring to CVS, Walmart, Walgreens,

1 Rite Aid and Giant Eagle?

2 A. Yes.

3 Q. Thank you very much. The way we have
4 met before is at a prior deposition. You have
5 testified before, correct, under oath?

6 A. That's correct.

7 Q. And would you state your full name
8 for the record? Just --

9 A. Katherine Keyes.

10 Q. And you understand that you are under
11 oath today, Professor Keyes?

12 A. I do.

13 Q. And if you don't understand one of my
14 questions, please just let me know and I will do my
15 best to ask it in a way that you can understand it,
16 okay?

17 A. Yes.

18 Q. And if I ask a question and you give
19 an answer, I will take that as an indication that
20 you understood my question; is that fair?

21 A. That is fair.

22 Q. Any reason you can think of that you
23 won't be able to answer my questions fully and
24 accurately today?

25 A. No.

1 Q. If you need to take a break at any
2 time, please just let me know and we can take a
3 break as long as there's not a question pending,
4 okay?

5 A. Yes.

6 Q. Did you do anything to prepare for
7 your deposition today?

8 A. I had meetings with plaintiffs'
9 counsel.

10 Q. About how many meetings did you have
11 with plaintiffs' counsel?

12 A. Two.

13 Q. And how long did those meetings last?

14 A. Approximately two hours each.

15 Q. Have you done the work that you feel
16 you need to do in order to testify here today?

17 A. I believe so.

18 Q. Have you done the work you need to do
19 in order to be able to testify before the jury at
20 trial?

21 A. I believe so.

22 Q. Is there any data that you wanted
23 that you did not have in writing your report?

24 A. No.

25 (Exhibit 1 was marked for

1 identification.)

2 Q. (BY MR. HERMAN:) Let's go ahead and
3 mark Exhibit 1, which will be a copy of your
4 report, dated April 16th, 2021.

5 Exhibit 2, which is the exhibits to
6 your report. And those should be in the sealed
7 envelopes marked CVS 1 and CVS 2.

8 (Exhibit 2 was marked for
9 identification.)

10 Q. (BY MR. HERMAN:) If you want to go
11 ahead.

12 A. Go ahead --

13 Q. Yeah, thank you.

14 (Exhibit 3 was marked for
15 identification.)

16 MR. HERMAN: And we are also going to
17 mark as Exhibit 3 -- and I am not sure -- it won't
18 be there in paper copy, but it is a supplemental
19 materials considered list that was sent to us last
20 night.

21 Q. (BY MR. HERMAN:) Dr. Keyes, have you
22 opened --

23 A. I am opening Exhibit 2.

24 Q. Just let me know when you have them.
25 It is not as easy as when I can hand it across the

1 table.

2 A. The tape is really tight.

3 Q. I did not tape it, but I apologize.

4 A. I have the exhibit.

5 Q. Okay. And is Exhibit 1 a copy of
6 your expert report that you submitted on April
7 16th, 2021?

8 A. Yes.

9 Q. And that is a report you wrote for
10 this case?

11 A. Yes.

12 Q. Do you understand that when you wrote
13 the report, dated it and signed it that it was to
14 include all the opinions that you intend to offer
15 at trial?

16 A. Yes.

17 Q. Does your report contain all the
18 opinions you intend to offer in this case?

19 A. Yes.

20 Q. Do you have any corrections to make
21 to your report at this time?

22 A. I don't at this time.

23 Q. In your report, you cite with end
24 notes a number of materials. And my understanding
25 is those citations are to the materials that

1 support the statements and opinions in your report;
2 is that correct?

3 A. Yes.

4 Q. And those cited references are on
5 Pages 62 to 76 of your report?

6 A. Yes, the full references from the
7 footnotes are on Page 62 to 76.

8 Q. Okay. And besides the materials that
9 you cited as footnotes and your background and
10 experience, are you relying on anything else to
11 support the opinions in your report?

12 A. In addition to the materials
13 considered list.

14 Q. Okay. When we were last together, I
15 guess, your materials considered list is, I
16 believe, seventeen hundred items long.

17 When we were last together, I think
18 you told me that those were materials that you had
19 reviewed, but the ones that were germane to your
20 opinions are the ones that you cited in the end
21 notes to your report. Is that still the case?

22 A. I would say that the citations that
23 are listed in the report form the basis of many of
24 my opinions, although I also considered the
25 additional sources that are on the materials

1 considered list as well.

2 So I would -- I would say both were
3 important in informing my opinions.

4 Q. And I mean you recognize that your
5 materials to consider list contains -- and that is
6 Exhibit -- well, let's go and do this this way: So
7 Exhibit 2 is your exhibits to your report in this
8 case, correct?

9 A. Yes, it is my CV --

10 Q. That is Exhibit A?

11 A. And Exhibit B is the materials
12 considered list, yes.

13 Q. And the materials considered list
14 contains, I believe, seven -- one thousand seven
15 hundred and seventy-eight numbered items?

16 A. Yes, it does.

17 Q. And on that list it appeared to me
18 that there were materials that you had considered
19 not just in connection with this case but materials
20 that you considered in connection, for example,
21 with the Cabell County, West Virginia case,
22 correct?

23 A. Yes. And other counties as well.

24 Q. Okay. And so, for example, Number 86
25 is related to hospital standard charges in Cabell

1 County, West Virginia, right?

2 A. Number 86, Cabell-Huntington Hospital
3 standard charges.

4 Q. And does that relate to your opinions
5 in this case? That relates to -- well, this case
6 is -- let me ask you this: You understand this
7 case relates to Lake and Trumbull County, Ohio?

8 A. I do.

9 Q. So does that material considered
10 Number 86 relate in any way to the opinions you are
11 giving in this case?

12 A. I would say that, you know, as I have
13 developed expertise across these counties, really
14 considering and comparing, it helps me to form a
15 general opinion about, you know, the extent and
16 burden of opiate use disorder and other related
17 overdose problems across counties.

18 So I didn't use Cabell data to inform
19 my estimates about Lake and Trumbull but generally
20 considering material from across counties is
21 actually very helpful in developing my opinions
22 more generally.

23 Q. And I think the last time we were
24 together, when I asked you about some of the
25 depositions, and there are a number of depositions

1 listed on your chart, you said you had looked at
2 some of them to some degree, but you hadn't read
3 them in full -- all of them in full. Is that still
4 the case today?

5 MR. ARBITBLIT: Objection, vague.

6 A. Yeah, I have looked at a number of
7 depositions. And the extent to which I reviewed
8 them depends on the specific deposition and how I
9 was using it to inform my opinions.

10 Q. (BY MR. HERMAN:) Okay. All right.
11 Well, you do recognize that the materials listed on
12 your materials considered list is probably
13 thousands of pages of material?

14 A. Yes.

15 Q. And is it your testimony that you
16 reviewed all that material carefully?

17 A. It really depends on the specific
18 material. Some material requires a more careful
19 review than other material. Some material I could
20 review and know rather quickly the extent to which
21 it was helpful in forming my opinion. So it really
22 depended on the source.

23 Q. But as a general matter, if I want to
24 understand what you are relying on to support the
25 statements in your report, I should look at the

1 materials that you cited as end notes in the
2 report, correct?

3 MR. ARBITBLIT: Objection, vague.

4 A. I would say both the end notes and
5 the materials considered list would be potential
6 sources that informed my opinions.

7 Q. (BY MR. HERMAN:) Okay. Exhibit D is
8 a list of the cases where you -- Exhibit D to
9 Exhibit 2 of this deposition is a list of the cases
10 where you provided testimony. Is that correct?

11 A. Is that in a separate -- I only have
12 through Exhibit C as part of Exhibit 2.

13 Q. Okay. Well, let me just try it this
14 way, then. I don't know why that last two pages is
15 not attached to yours, but -- you testified in a
16 case involving Cuyahoga and Summit County, correct?

17 A. Correct.

18 Q. Okay. And you testified there under
19 oath?

20 A. Yes.

21 Q. And did you have an opportunity to
22 review that transcript after your deposition?

23 A. I did.

24 Q. And you also testified in a case that
25 involved Suffolk County, Nassau County and the

1 State of New York?

2 A. Yes.

3 Q. And you gave a deposition in that
4 case?

5 A. I did.

6 Q. And you also testified at a hearing
7 before Judge Garguilo?

8 A. I did.

9 Q. And your testimony in that case, both
10 at your deposition and at the hearing, were under
11 oath?

12 A. Yes.

13 Q. Did you review your transcripts?

14 A. Yes.

15 Q. And you have also testified at a case
16 involving Cabell County and the City of Huntington,
17 West Virginia; is that correct?

18 A. Yes.

19 Q. And in that case you gave two
20 depositions?

21 A. Yes.

22 Q. And both of those depositions were
23 under oath?

24 A. Yes.

25 Q. And did you have a chance to review

1 your transcript for both those depositions?

2 A. Yes.

3 Q. Going back to your report in this
4 case, your report in this case doesn't mention CVS,
5 Rite Aid, Walgreens, Walmart or Giant Eagle,
6 correct?

7 A. That's correct.

8 Q. You didn't consider any document
9 produced by CVS in this case or any other, correct?

10 A. As far as I know, no document
11 produced by the -- the defendants.

12 Q. Okay. And when you say "the
13 defendants," you are including in that CVS,
14 Walgreens, Walmart, Rite Aid and Giant Eagle?

15 A. Yes.

16 Q. You didn't review any -- the
17 deposition of any CVS employee, correct?

18 A. That's correct.

19 Q. You didn't review the deposition of
20 any Walgreens, Walmart, Rite Aid or Giant Eagle
21 employee, correct?

22 A. That's correct.

23 Q. I searched your report for the words
24 "CVS," "Rite Aid," "Walgreens," "Walmart" and
25 "Giant Eagle," and they don't appear anywhere in

1 your report, correct?

2 A. I include various data sources that
3 provide aggregate information on retail pharmacies
4 across the United States.

5 Q. Any pharmacy, correct, any retail
6 pharmacy?

7 A. On a wide variety of pharmacies.

8 Q. That is true, the word "pharmacy"
9 does appear six times in your report. Does that
10 sound about right?

11 MR. ARBITBLIT: Objection, vague.

12 A. I have not done -- right. I have not
13 done a check on the word "pharmacy," but there is
14 considerable information about pharmacies in the
15 report.

16 Q. (BY MR. HERMAN:) But you don't
17 specifically mention CVS, Rite Aid, Walgreens,
18 Walmart or Giant Eagle in your report, correct?

19 A. That is correct.

20 Q. You don't intend to offer any
21 opinions specific to CVS, correct?

22 A. To the extent that I offer opinions
23 about pharmacies, I would include CVS as one of
24 them. But I don't have any specific opinions about
25 CVS uniquely.

1 Q. Well, I think we are saying the same
2 thing. You are not going to offer opinions
3 specific to CVS in this case, correct?

4 MR. ARBITBLIT: Objection. Asked and
5 answered.

6 A. I offer opinions about the pharmacies
7 overall. There is nothing that is specific to any
8 particular pharmacy chain.

9 Q. (BY MR. HERMAN:) And just so the
10 record is clear, when you say "specific to any
11 pharmacy chain," you are including in that
12 Walgreens, Walmart, Rite Aid and Giant Eagle?

13 A. That's correct.

14 Q. Professor Keyes, this may be a
15 somewhat silly question, but have you ever worked
16 in a pharmacy?

17 A. I have never worked in a pharmacy.

18 Q. You don't hold yourself out as an
19 expert in the practice of pharmacy?

20 A. I have expertise in the epidemiology
21 of pharmacological distribution and harms
22 associated with medications that are dispensed from
23 pharmacies.

24 Q. Okay. But you yourself have never
25 practiced pharmacy?

1 A. I am not a pharmacist.

2 Q. And are you an expert in the laws and
3 regulations that apply to pharmacies?

4 A. I have expertise and knowledge based
5 on my epidemiological background on laws and
6 regulations as they apply to pharmacies.

7 Q. So do you hold yourself out as an
8 expert in the Controlled Substances Act?

9 A. I hold myself out as an expert in
10 policies and laws as they relate to pharmacies,
11 which would include the Controlled Substances Act.

12 Q. And -- okay. You are not evaluating
13 whether any specific prescription was written by a
14 prescriber for a legitimate medical purpose in this
15 case, are you?

16 A. No. Oh, yes. I'm sorry. I was -- I
17 am not providing any opinions about specific
18 prescriptions, right.

19 Q. So just so the record is clear,
20 because I think -- okay. I think that is clear.

21 Are you aware of any prescription
22 opioid improperly dispensed by a CVS pharmacy in
23 Lake or Trumbull County?

24 A. I have not evaluated information
25 related to specific prescription opioids dispensed

1 in Lake or Trumbull County.

2 Q. Okay. And you didn't look at what
3 happened to any specific patient who filled a
4 prescription at any pharmacy in Lake or Trumbull
5 County, correct?

6 A. That is correct.

7 Q. You are not opining that a specific
8 prescription dispensed in Lake County led to harm?

9 A. I have not evaluated specific
10 prescription information, so I am not opining
11 that -- about any specific prescription in a
12 singular. I am opining about the aggregate.

13 Q. And you are not opining about any
14 specific patient who filled a prescription either,
15 correct?

16 A. That is correct.

17 Q. Okay. Prescription opioids are
18 medications approved for medical use by the United
19 States Food and Drug Administration, correct?

20 A. Yes.

21 Q. And to this day, prescription opioids
22 are approved by the FDA for medical use in the
23 United States, correct?

24 A. Yes.

25 Q. Have you heard of the Center For Drug

1 Evaluation and Research?

2 A. Yes.

3 Q. And is that part of the FDA?

4 A. Yes.

5 Q. Can I ask you to go ahead and open up
6 CVS 3? And I think we will mark that as Exhibit 4.

7 (Exhibit 4 was marked for
8 identification.)

9 Q. (BY MR. HERMAN:) Do you have that
10 open now?

11 A. I do.

12 Q. Okay. And Exhibit 4 is a printout
13 from the FDA's website on the Development and
14 Approval Process. Do you see that?

15 A. I see the document that has been
16 given to me. I haven't verified.

17 Q. But if you look down at the bottom of
18 the page, do you see a website that says
19 [https://www.fda.gov/drugs/development-approval-
process-drugs?](https://www.fda.gov/drugs/development-approval-
20 process-drugs?) Do you see that?

21 A. I do, yeah.

22 Q. Does that indicate to you that this
23 was printed out off the FDA's government website?

24 A. Yes.

25 Q. And if you look at the top, second

1 paragraph in, it says, "The center's best-known job
2 is to evaluate new drugs before they can be sold.
3 CDER's evaluation not only prevents quackery but
4 also provides doctors and patients information they
5 need to use medicines wisely. The center ensures
6 that drugs, both brand name and generic, work
7 correctly and that their health benefits outweigh
8 their known risks." Did I read that correctly?

9 A. That is what is written.

10 Q. And do you understand that CDER to be
11 an abbreviation for the Center -- I'm sorry, for
12 the Center for Drug Evaluation and Research?

13 A. Yes.

14 Q. Okay. And so the FDA says on its
15 website that one of its roles is to provide doctors
16 and patients information needed to use medicines
17 wisely?

18 A. That is what the FDA says on their
19 website.

20 Q. And the FDA says that CDER ensures
21 that drugs work correctly and that their health
22 benefits outweigh their known risks?

23 MR. ARBITBLIT: Objection. The
24 document speaks for itself. There's no point just
25 reading the document with the witness.

1 Q. (BY MR. HERMAN:) You can answer my
2 question.

3 A. I see that written on this page.

4 Q. On the FDA's website?

5 A. Yes.

6 Q. Okay. And if you go down under the
7 heading "FDA Approval: What it Means," it says,
8 "FDA approval of a drug means that data on the
9 drugs' effect have been reviewed by CDER and the
10 drug is determined to provide benefits that
11 outweigh its known and potential risks for the
12 intended population."

13 MR. ARBITBLIT: Same objection.

14 Q. (BY MR. HERMAN:) Did I read that
15 correctly?

16 A. Yes, it was read correctly.

17 Q. So the FDA states on its website that
18 its approval of a prescription opioid medication
19 means that it has determined that the benefit of
20 prescription opioids outweigh the potential risks
21 for the treatment of moderate to severe pain?

22 MR. ARBITBLIT: Same objection.

23 A. That is not what is written here.

24 Q. (BY MR. HERMAN:) Well, I apologize.
25 Why don't we go to Page 5 of your report. And just

1 directing your attention to the definition of
2 prescription opioids. In your report you define
3 prescription opioids as "Drugs approved for medical
4 use in the United States for control of moderate to
5 severe pain that are either natural opiate
6 analgesics derived from opium (morphine and
7 codeine), semisynthetic opioid analgesics
8 (oxycodone, hydrocodone, hydromorphone and
9 oxymorphone), synthetic opioids (methadone) or
10 synthetic opioid analgesics (e.g., tramadol and
11 fentanyl)." Is that how you define prescription
12 opioids?

13 A. Yes.

14 Q. So your definition of prescription
15 opioids recognizes that they have been approved by
16 the FDA for medical use in the United States for
17 the control of moderate to severe pain, correct?

18 A. Yes.

19 Q. And I said "they" there. Just to be
20 clear, I was referring to prescription opioids; you
21 understood that, right?

22 A. Yes.

23 Q. And so if you would -- if you take
24 your definition and what the FDA says approval
25 means, would you agree with me that the FDA

1 approval means that prescription opioid
2 medications -- that the FDA has determined that the
3 benefits of prescription opioids outweigh their
4 potential risk for the treatment of moderate to
5 severe pain?

6 A. I have not evaluated the specific FDA
7 determination on specific opioid products. I do
8 agree that the FDA has approved prescription
9 opioids and that what is written on this page
10 describes very generally the approval process in a
11 very high level way. But I wouldn't concede
12 that -- without having reviewed the FDA's actual
13 material on opioids, I would not offer an opinion
14 about the FDA's approval process of opioids.

15 Q. But your definition at least
16 recognizes that they have been approved for
17 treatment of moderate to severe pain, correct?

18 A. Yes.

19 Q. And the FDA states on its website
20 that its "evaluation of each prescription opioid
21 medication provides the doctors and patients with
22 information needed to use the medication wisely."

23 MR. ARBITBLIT: Objection. The
24 document speaks for itself.

25 A. Yes, that is stated on the website.

1 Q. (BY MR. HERMAN:) Okay. And can I
2 ask you to go to the next page, 2 of 4, to the
3 section "Strategies for Managing Risks." And the
4 first sentence -- the first and second sentence
5 there say, "All drugs have risks. Risk management
6 strategies include an FDA-approved drug label which
7 clearly describes the drug's benefits and risks and
8 how the risk can be detected and managed." Did I
9 read that correctly?

10 MR. ARBITBLIT: The document speaks
11 for itself.

12 A. Yes, it was read correctly.

13 Q. (BY MR. HERMAN:) Are you aware that
14 the FDA approved a warning label for each
15 prescription opioid medication?

16 A. I have not evaluated and don't offer
17 opinions on specific FDA warning labels for opioid
18 medications.

19 Q. Well, I am asking, I think, a
20 slightly different question. You do have an
21 understanding that each prescription opioid
22 medication has a warning label approved by the FDA?

23 A. Yes.

24 Q. Is it your understanding that the
25 expectation is that prescribers will review the

1 warning labels and utilize the information when
2 deciding whether to prescribe prescription opioids?

3 MR. ARBITBLIT: Objection, vague.
4 Speculative.

5 A. Yes. I am not offering an opinion
6 about what prescribers review vis-à-vis warning
7 labels.

8 Q. (BY MR. HERMAN:) Well, is it your
9 understanding that one of the purposes of the FDA
10 warning label for any medication is that
11 prescribers will review that warning label to
12 better understand the risks and benefits of the
13 medication?

14 MR. ARBITBLIT: Objection, vague.
15 Overbroad.

16 A. I have not evaluated documents
17 regarding the purpose of the FDA warning label, so
18 I would not offer an opinion on that.

19 Q. (BY MR. HERMAN:) Okay. You don't
20 have any understanding of the purpose of an FDA
21 warning label?

22 MR. ARBITBLIT: Objection.
23 Argumentative.

24 A. I have not evaluated any specific
25 material on the purpose of FDA warning labels, so I

1 would not -- I would not offer an opinion about
2 what prescribers do vis-à-vis specific warning
3 labels regarding opioids.

4 Q. (BY MR. HERMAN:) What is your
5 understanding of the purpose of an FDA-approved
6 warning label?

7 A. I believe that it is -- you know, the
8 document here states very clearly that the purpose
9 of the warning label is to provide information
10 about potential risks and side effects.

11 Q. Okay. And like its name suggests, it
12 is intended to be a warning that doctors will
13 review before prescribing medication, right?

14 MR. ARBITBLIT: Objection,
15 speculative.

16 A. I think there are numerous reasons to
17 have a warning label, and I would not offer an
18 opinion about the -- what specific doctors and
19 prescribers do with those warning labels.

20 Q. (BY MR. HERMAN:) Do you agree that
21 approval by the FDA of prescription opioid
22 medications was a necessary condition for there to
23 be a supply of prescription opioids?

24 A. Not in an absolute sense.

25 Q. Well, without approval of

1 prescription opioids by the FDA, no doctor would
2 prescribe opioids to patients, correct?

3 A. That is correct.

4 Q. And CVS, Rite Aid, Walmart,
5 Walgreen's and Giant Eagle's pharmacies would not
6 have prescription opioids in their pharmacies if
7 they were not approved by the FDA as medications,
8 correct?

9 A. That's correct.

10 Q. Professor Keyes, do you fault the FDA
11 for approving prescription opioids for medical use?

12 A. I think, in general, when you look at
13 the drivers of the opioid crisis and the overdose
14 crisis, that certainly the role of the FDA in
15 evaluating the risks and benefits of opioid
16 medications is part of the larger constellation of
17 factors that contributed to the opioid crisis.

18 Q. And so am I understanding you
19 correctly that with information you have today, you
20 do not believe that the FDA evaluated the risks and
21 benefits of the opioid medications appropriately?

22 A. That is a very general statement. I
23 would -- I would certainly -- I think that one
24 could reevaluate the information that the FDA
25 received, but I would need to look at each specific

1 drug in determining the appropriateness of FDA
2 conclusions.

3 Q. And you would have to look at each
4 different drug because there are different types of
5 prescription opioids, correct?

6 MR. ARBITBLIT: Objection, vague,
7 overbroad.

8 A. There are different types of
9 prescription opioids.

10 Q. (BY MR. HERMAN:) And different types
11 of prescription opioid medications have different
12 risks and benefits?

13 MR. ARBITBLIT: Objection. Vague and
14 overbroad.

15 A. There are different types of opioid
16 medications -- each one would need to be evaluated
17 in terms of their risks and benefits separately.

18 Q. (BY MR. HERMAN:) If you were in
19 charge of the FDA, would you have approved
20 prescription opioids for medical use?

21 MR. ARBITBLIT: Objection, vague,
22 speculative, overly broad.

23 A. That is a hypothetical that I can't
24 answer. I am not in charge of the FDA, so I can't
25 answer what I would have done had I been in charge

1 of the FDA.

2 Q. (BY MR. HERMAN:) I am asking you to
3 answer that hypothetical.

4 MR. ARBITBLIT: Incomplete
5 hypothetical. Same objection plus incomplete
6 hypothetical.

7 Q. (BY MR. HERMAN:) Dr. Keyes, if you
8 were in charge of the FDA, would you have approved
9 prescription opioids for medical use?

10 MR. ARBITBLIT: Same objection.

11 A. I would need to look at each -- I
12 would need to review the documents for each
13 specific product to answer that question, which I
14 have not done.

15 Q. (BY MR. HERMAN:) Okay. Sitting here
16 today, you don't know whether you would have
17 approved or banned prescription opioids for medical
18 use?

19 MR. ARBITBLIT: Objection, vague,
20 overbroad, hypothetical.

21 A. I would need to review the specific
22 documents in order to engage in that hypothetical,
23 which I have not done.

24 Q. (BY MR. HERMAN:) So is the answer to
25 my question no, that sitting here today you cannot

1 state whether you would ban or approve prescription
2 opioids if you were in charge of the FDA today?

3 MR. ARBITBLIT: Same objection and
4 asked and answered.

5 A. I would say that the broad
6 hypothetical of all prescription opioids and the
7 inconclusive language of ban or approve is not
8 something that anyone, including, you know, people
9 in charge of the FDA, could answer in an absolute
10 way.

11 Q. (BY MR. HERMAN:) It is a complicated
12 question?

13 MR. ARBITBLIT: Object to the form.

14 A. I don't think it is a complicated
15 question. I think it is a hypothetical that is too
16 broad.

17 Q. (BY MR. HERMAN:) Can I ask you to
18 take out what has been marked as Exhibit 7-1 in the
19 envelope, and it will be Exhibit 5 to this
20 deposition.

21 (Exhibit 5 was marked for
22 identification.)

23 Q. (BY MR. HERMAN:) Do you have that or
24 do you have that exhibit?

25 A. I do.

1 Q. And is Exhibit 5 the CDC guidelines
2 that were issued in 2016?

3 A. They are a set of guidelines that
4 were published in 2016 by the CDC.

5 Q. And they are a set of guidelines on
6 prescribing opioid medications that were published
7 in 2016?

8 A. They are recommendations for primary
9 care clinicians who are prescribing opiates for
10 chronic pain outside of active cancer treatment,
11 palliative care and end of life care. So just to
12 be more specific, that is the scope of the
13 guidelines.

14 Q. Okay. And you cite these in your
15 expert report as it is referenced, 152?

16 A. Let me just check.

17 (Pause.)

18 A. Yes.

19 Q. (BY MR. HERMAN:) And were the 2016
20 guidelines the first guidelines put out by the CDC
21 on prescribing opioid medications?

22 A. I'm not sure. I would need to look
23 at that.

24 Q. Do you know if the 2016 CDC
25 guidelines were the first federal guidelines on

1 prescribing opioids?

2 A. I don't know.

3 Q. Dr. Keyes, I think in your report you
4 recognize that prescribing of opioids has been
5 decreasing for approximately ten years. Is that
6 correct? Since 2012?

7 A. Is there a place in the report that I
8 can --

9 Q. Well, let me ask in the abstract. Do
10 you know when the prescribing -- when generally the
11 prescribing of opioids began to decrease in the
12 United States?

13 A. I would want to look at my report to
14 make sure I am testifying correctly. Is there a
15 place in the report that I can -- I just want to
16 make sure I am giving the most accurate
17 information.

18 Q. We can come back to that. You don't
19 know off the top of your head?

20 A. I just want to make sure because this
21 is important that I am accurately citing the right
22 reference and conveying the right information for
23 the record. And so I would prefer, and be more
24 comfortable, if you could point to where in the
25 report that is stated so I can appropriately

1 testify.

2 Q. Okay. So if you look at Page 45, at
3 the top, and there's a sentence there that
4 recognizes that prescribing began to decrease in
5 2012. Do you see that sentence?

6 A. The sentence is "Prescribing then
7 began decreasing, although remains extraordinarily
8 high."

9 Q. Okay. But you recognize that
10 prescribing began to decrease in 2012, correct?

11 A. Right. From the height of 2012.

12 Q. And has prescribing of prescription
13 opioids continued to decrease since 2012?

14 A. Nationally or in Lake and Trumbull
15 County?

16 Q. Well, let's start with nationally.

17 A. Nationally, prescription opioid use
18 has declined, although it remains much higher than
19 preopioid epidemic levels. So, yes, there have
20 been declines since 2012, but the level of
21 prescribing remains much higher than it was prior
22 to the opioid crisis.

23 Q. And when higher -- when you say
24 "higher than," can you give me a year when you are
25 comparing it to?

1 A. The sources that I cite in this
2 report began in about the mid 1990s.

3 Q. Do you know if opioid prescribing had
4 began to increase before the mid 1990s?

5 A. In the sources that I have evaluated,
6 most of the -- the sources that I have evaluated
7 began in the early to mid 1990s. So I am not -- I
8 have not evaluated carefully sources prior to the
9 early to mid 1990s.

10 Q. Okay. And can I ask you -- I think I
11 know the answer to this based on your past
12 testimony. But if you look at Exhibit 5, first
13 sentence of Background, it says opioids are
14 commonly prescribed for pain. Do you agree that
15 opioids are a commonly prescribed medication for
16 pain?

17 A. I agree that opioids are commonly
18 prescribed for pain.

19 Q. And you have been talking a little
20 bit about the rate of prescribing. Do you
21 understand that to mean that licensed prescribers
22 often prescribe opioids for their patients' pain?

23 MR. ARBITBLIT: Objection.
24 Speculative.

25 A. I understand that -- that opioids are

1 prescribed often for pain by licensed prescribers,
2 yes.

3 Q. (BY MR. HERMAN:) And can I direct
4 your attention to the second paragraph of Exhibit
5 5.

6 MR. HERMAN: Is there any way we can
7 put that up?

8 Q. (BY MR. HERMAN:) Do you see where it
9 says, "Prevention, assessment and treatment of
10 chronic pain are challenges for health providers
11 and systems. Pain might go unrecognized and
12 patients, particularly members of racial and ethnic
13 minority groups, women, the elderly, persons with
14 cognitive impairment and those with cancer and at
15 the end of life, can be at risk for inadequate pain
16 treatment." Do you see where I am reading?

17 A. I do.

18 Q. Did I read that correctly?

19 A. Yes.

20 MR. ARBITBLIT: Objection. The
21 document speaks for itself.

22 Q. (BY MR. HERMAN:) And is it your
23 understanding that the CDC is expressing a concern
24 that pain might go unrecognized and untreated in
25 2016?

1 MR. ARBITBLIT: Objection. The
2 document speaks for itself, and it is speculative
3 as to what the CDC is thinking.

4 A. I can read what is on the page. This
5 document, coauthored by three people through the
6 CDC, states that there can be persons who are at
7 risk for inadequate pain treatment.

8 Q. (BY MR. HERMAN:) I found it
9 interesting that pain going unrecognized was a
10 particular concern to women. Do you know why that
11 would be the case, Professor Keyes?

12 MR. ARBITBLIT: Object to the form.

13 A. I guess I don't understand the
14 question. Is the question, is it interesting that
15 pain goes unrecognized?

16 Q. (BY MR. HERMAN:) Oh, no, I'm sorry.
17 Let's get rid of my discussion of that point.

18 I just want to know, do you know why
19 it would be the case that pain would be of
20 particular concern for going unrecognized for
21 women?

22 A. I'm not sure what specifically the
23 CDC authors are referring to when they highlight
24 women as a risk group there.

25 Q. Would your answer be the same for

1 ethnic and racial minority groups?

2 A. I believe what the purpose of the
3 sentence is is that the sentence is saying pain may
4 go unrecognized and that that might be different by
5 these different demographic groups, and that would
6 include racial and ethnic minorities and women and
7 the other groups highlighted in that sentence.

8 Q. Yeah, I understood it to be saying
9 that these groups can be particularly at risk for
10 inadequate pain treatment. Is that how you
11 understand it or --

12 MR. ARBITBLIT: Object to the form.

13 A. That is not exactly what the sentence
14 says. It says that those groups can be at risk for
15 inadequate pain treatment, based on the CDC --
16 these authors' assessment.

17 Q. (BY MR. HERMAN:) Okay. And these
18 authors' assessment published by the CDC?

19 A. Yes.

20 MR. ARBITBLIT: Object to the form.

21 Q. (BY MR. HERMAN:) And if you look at
22 the next sentence, it says, "Patients can
23 experience persistent pain that is not
24 well-controlled. There are clinical, psychological
25 and social consequences associated with chronic

1 pain, including limitations in complex activities,
2 lost work productivity, reduced quality of life and
3 stigma, emphasizing the importance of appropriate
4 and compassionate patient care."

5 Do you see where I just read?

6 A. I do.

7 Q. Did I read that correctly?

8 A. Yes.

9 Q. Do you agree with the CDC that there
10 are clinical, psychological and social consequences
11 associated with chronic pain?

12 A. There certainly can be consequences
13 of chronic pain, including clinical, psychological
14 and social.

15 Q. And do you understand the CDC to be
16 saying here because of clinical -- sorry --
17 sociological and social consequences associated
18 with chronic pain, that emphasis should be placed
19 on the importance of appropriate and compassionate
20 care?

21 A. I think -- do -- you are asking what
22 I understand the CDC to be saying? I don't want to
23 speculate about what the CDC meant in that
24 statement. I am not the authors.

25 Q. Would you agree with the sentiment

1 that because there are clinical, psychological and
2 social consequences associated with chronic pain,
3 that emphasis should be placed on the importance of
4 appropriate and compassionate patient care?

5 A. All patients, regardless of their
6 condition, should be treated with appropriate and
7 compassionate care. And there's a lot of
8 discussion about the level -- what constitutes
9 appropriate care in the context of chronic pain.

10 Q. And I think the -- and can I ask you
11 to go to Page 2? And if you look just above
12 "Rationale," do you see where it says, "Clinical
13 decision-making should be based on a relationship
14 between the clinician and patient and understanding
15 of the patient's clinical situation, functioning
16 and life context. The recommendations in the" --
17 well, let's stop.

18 "The recommendations in the guideline
19 are voluntary rather than prescriptive standards.
20 They are based on emerging evidence, including
21 observational studies or randomized clinical trials
22 with notable limitations. Clinicians should
23 consider the circumstances and unique needs of each
24 patient when providing care."

25 MR. ARBITBLIT: Objection. The

1 document speaks for itself. No question pending.

2 Q. (BY MR. HERMAN:) Do you see where I
3 just read?

4 MR. ARBITBLIT: Same objection.

5 A. I see that that is what is written.

6 Q. (BY MR. HERMAN:) And did I read that
7 correctly?

8 A. You read that correctly.

9 Q. Clinical decisions are decisions made
10 by prescribers, correct?

11 MR. ARBITBLIT: Objection.

12 A. Clinical decisions can be made by
13 prescribers.

14 Q. (BY MR. HERMAN:) Do you agree that
15 the clinical decisions being referenced here are
16 clinical decisions made by prescribers?

17 MR. ARBITBLIT: Objection,
18 speculative. The document speaks for itself.

19 A. I wouldn't speculate on specifically
20 who the CDC was referring to in that sentence.
21 They just say "clinical decision-making." Clinical
22 decisions are made by a variety of care providers.

23 Q. (BY MR. HERMAN:) Well, these are
24 prescribing guidelines, are they not?

25 A. These are prescribing guidelines.

1 Q. And so you don't think that the
2 reference to clinical decisions is a reference to
3 the prescriber, decisions made by prescribers?

4 MR. ARBITBLIT: Objection,
5 speculative. Asked and answered. Argumentative.

6 A. I am not speculating on who --
7 they -- I am reading the text, as you are. They
8 discuss the dose response relationship between
9 opioid use and overdose and then say that clinical
10 decision-making should be based on a relationship
11 between a clinician and a patient. They do not
12 specify provider.

13 Q. (BY MR. HERMAN:) Okay. Right in the
14 next sentence it says -- let me ask you this:
15 Dr. Keyes, you understand that a doctor is only
16 supposed to write a prescription for a legitimate
17 medical purpose, correct?

18 MR. ARBITBLIT: Object to form.
19 Speculative.

20 A. I don't want to speculate about what
21 every doctor writes prescriptions for.

22 Q. (BY MR. HERMAN:) Well, I am not
23 asking you about why the doctor does it. But I am
24 asking you -- well, let me ask you this: You said
25 earlier that you had familiar -- familiarity and

1 expertise with the CSA and related laws and
2 regulations, correct?

3 A. Yes.

4 Q. Okay. So do you understand that a
5 doctor is only supposed to write a prescription for
6 a legitimate medical purpose?

7 MR. ARBITBLIT: Object to form.

8 A. I would ask what you mean by a
9 legitimate medical purpose. There's -- doctors
10 write prescriptions based on information that they
11 have.

12 Q. (BY MR. HERMAN:) You understand that
13 that is the language used in the CDC, that a
14 practitioner is only supposed to write a
15 prescription for a legitimate medical purpose in
16 the usual course of practice?

17 A. Is this a specific CDC document?

18 Q. Well, it is a specific law and
19 regulation. I thought earlier you said you had
20 expertise in the CSA and laws and regulations.

21 MR. ARBITBLIT: Objection.

22 A. From the CDC?

23 Q. (BY MR. HERMAN:) No, from the
24 federal government.

25 MR. ARBITBLIT: Objection.

1 Misstates.

2 A. So your previous question was about
3 language used by the CDC. So my question is --

4 Q. (BY MR. HERMAN:) No. My --

5 A. -- if there's a specific --

6 Q. (BY MR. HERMAN:) I'm sorry. I
7 didn't mean to interrupt. My previous question was
8 you understand that a doctor is only supposed to
9 write a prescription for a legitimate medical
10 purpose, correct?

11 MR. ARBITBLIT: Objection, vague.

12 A. My understanding is that physicians
13 write prescriptions based on the information that
14 they have about the patient and that -- and that
15 they use that information in writing prescriptions.

16 Q. (BY MR. HERMAN:) Well, let's see if
17 we can agree. Would you agree that the doctor,
18 based on information the doctor has, is supposed to
19 write a prescription in good faith for a legitimate
20 medical purpose?

21 A. I think that there is a wide variety
22 of opinions about the medical purposes for which
23 opioids would be an effective therapy. And so two
24 doctors could have differences of opinion about the
25 specific medical purpose for which an opioid would

1 be indicated. Therefore, my opinion is that
2 physicians write prescriptions based on the
3 information that has been provided to them.

4 Q. So I understood you to be saying --
5 you said different physicians might evaluate a
6 prescription differently, correct?

7 MR. ARBITBLIT: Objection. Misstates
8 the testimony.

9 Q. (BY MR. HERMAN:) Well, you said two
10 doctors could have differences of opinions about
11 the specific medical purpose for which an opioid
12 would be indicated, correct?

13 A. I said that two doctors could have
14 differences, yes, about the specific medical
15 purpose for which an opioid would be indicated.

16 Q. That is because doctors might
17 evaluate the risks and benefits of a prescription
18 opioid differently?

19 MR. ARBITBLIT: Object to form.

20 A. That is not what I testified.

21 Q. (BY MR. HERMAN:) Okay. Well, what
22 do you mean when you say two doctors could have
23 differences of opinions about the specific medical
24 purpose for which an opioid would be indicated?

25 A. I was referring in that statement to

1 the statement that doctors write prescriptions for
2 legitimate medical needs. My opinion is that the
3 word "legitimate" is fairly vague.

4 Q. Okay. So you think the term
5 "legitimate medical purpose" is too vague to
6 evaluate?

7 MR. ARBITBLIT: Object to form.

8 A. It is broad.

9 Q. (BY MR. HERMAN:) Different people
10 could evaluate it differently?

11 A. I think what we have seen from the
12 evidence, and I would just go back to my report, is
13 that -- is that the opioids that were dispensed
14 often went to the wrong people. And, therefore,
15 because you have this vast oversupply, it certainly
16 is indicative of a wide variety of dispensing and
17 prescribing practices and that legitimate medical
18 needs were not always the -- that opioids were not
19 prescribed always for legitimate medical needs
20 because there was such an oversupply and diversion.

21 Q. But do you have a reason to
22 believe -- well, let me -- let me ask you this: I
23 mean, do you believe that -- you talked earlier
24 about how doctors were prescribing based on the
25 information available to them. Do you believe that

1 the doctors who were prescribing based on the
2 information available to them intended that the
3 prescriptions would be used for a legitimate
4 medical purpose?

5 MR. ARBITBLIT: Objection, vague,
6 overbroad, speculative. Misstates the record.

7 A. I wouldn't offer an opinion about all
8 doctors and their intentions for prescribing.

9 Q. (BY MR. HERMAN:) I want to go back
10 to my question, because you have been sort of
11 focusing on the -- understanding the intention of
12 the doctor. But do you understand that a doctor is
13 only supposed to write a prescription for a
14 legitimate medical purpose?

15 MR. ARBITBLIT: Objection, vague.
16 Object to the prelude.

17 A. When -- I guess I am not
18 understanding what you mean by a doctor is supposed
19 to write a prescription. I think, as it says in
20 the CDC guidelines, clinicians and patients are in
21 conversation about various conditions. And so what
22 the intention of doctors are, what they are
23 supposed to do and what is actually done in a
24 clinical setting -- you know, I'm not sure what you
25 are asking.

1 Q. (BY MR. HERMAN:) Well, do you
2 understand that the federal regulations on
3 prescribing controlled substances state that a
4 practitioner should only prescribe controlled
5 substances for a legitimate medical purpose?

6 A. I do understand the federal
7 regulations on that -- on that issue.

8 Q. Okay. So you do have an
9 understanding that a doctor is only supposed to
10 prescribe a prescription opioid for a legitimate
11 medical purpose?

12 MR. ARBITBLIT: Objection, form.

13 A. My understanding of the federal
14 regulations is that controlled substances should be
15 prescribed for approved uses.

16 Q. (BY MR. HERMAN:) Okay. Do you
17 understand that it actually uses the term
18 "legitimate medical purpose"?

19 THE REPORTER: You need to speak up a
20 little bit, Mr. Herman.

21 MR. HERMAN: I apologize. I leaned
22 back.

23 Q. (BY MR. HERMAN:) Let me ask my
24 question again. Do you understand that the federal
25 regulation actually uses the term "legitimate

1 medical purpose"?

2 A. I would need to review the specific
3 document to understand it in context.

4 Q. Okay. Going back to the guidelines,
5 when it says that the guidelines are voluntary
6 rather than prescriptive standards, do you
7 understand that to mean they are not absolute
8 rules?

9 MR. ARBITBLIT: Object to form.

10 A. I would just refer to the document
11 itself. It says that they are voluntary rather
12 than prescriptive standards. And I wouldn't offer
13 an opinion about how those are interpreted -- how
14 those words are interpreted.

15 Q. (BY MR. HERMAN:) Okay. All right.
16 Well, do you understand that part of the reason
17 they are guidelines and not prescriptive standards
18 is explained in the next sentence, that "They are
19 based on emerging evidence, including observational
20 studies or randomized clinical trials" --

21 THE REPORTER: I can't understand you
22 well. Would you slow down when you are reading and
23 speak up?

24 MR. HERMAN: I apologize.

25 Q. (BY MR. HERMAN:) Do you understand

1 the next sentence, "They are based on emerging
2 evidence, including observational studies or
3 randomized clinical trials with notable
4 limitations," to be part of the explanation for why
5 the guidelines are not prescriptive standards?

6 MR. ARBITBLIT: Objection,
7 speculative.

8 A. Yeah, I don't -- I can't speak to
9 whether that sentence is being offered as part of
10 the previous sentence.

11 Q. (BY MR. HERMAN:) Okay. Well, the
12 CDC in that sentence recognizes that evidence
13 related to prescription opioids has changed over
14 time, correct?

15 A. I'm sorry. You are cutting out a
16 little bit.

17 SPECIAL MASTER COHEN: Mr. Herman,
18 I'm sorry. This is David Cohen. I just note that
19 your appearance on my screen is actually much
20 smaller than everyone else. And so I wonder if you
21 are a distance from the microphone and that is what
22 is causing the issue.

23 MR. HERMAN: I am a little bit of a
24 distance, but I haven't moved since the start. Can
25 people hear me now?

1 SPECIAL MASTER COHEN: Yeah. It has
2 actually been hard to hear from the start. So I am
3 just suggesting that if you get closer to the
4 microphone, it might be helpful.

5 MR. HERMAN: Okay. Do people want
6 to -- do people want to break for -- maybe just
7 take a break and maybe break for lunch now and I
8 could try to get this straightened out?

9 THE VIDEOGRAPHER: Sure. Stand by.
10 We are now off the record. The time on the video
11 monitor is 12:14.

12 (Whereupon, a lunch break was had
13 from 12:14 p.m. until 12:48 p.m. EDT)

14 THE VIDEOGRAPHER: We are now on the
15 record. The time on the video monitor is 12:48.

16 MR. HERMAN: Can we go off the record
17 for a second? I really apologize. I lost my
18 realtime because of whatever they changed. And so
19 I didn't realize that until just now. So --

20 THE VIDEOGRAPHER: Stand by.

21 MR. HERMAN: I apologize.

22 THE VIDEOGRAPHER: We are now off the
23 record. The time on the video monitor is 12:49.

24 (Whereupon, a break was had from
25 12:49 p.m. until 12:52 p.m. EDT)

1 THE VIDEOGRAPHER: We are now on the
2 record. The time on the video monitor is 12:52.

3 (Exhibit 6 was marked for
4 identification.)

5 Q. (BY MR. HERMAN:) Dr. Keyes, can I
6 ask you to open CVS 5? And Exhibit 5 is an article
7 on which you were an author, titled "A Critical
8 Review of the Social and Behavioral Contributions
9 to the Overdose Epidemic" that was published in --
10 on November 30th, 2020. Is that correct?

11 A. Yes.

12 Q. And can I ask you to turn to Page 97?
13 And under "Supply Drivers of the Overdose
14 Epidemic," this article states, "Supply drivers
15 include the proliferation of opioids prescribing to
16 treat chronic pain, as well as changes in the
17 heroin and the illegally manufactured opioid
18 synthetics market." Is that correct?

19 A. That's correct.

20 Q. And so this article says there were
21 two -- the two supply drivers discussed are, one,
22 more prescribing and, two, changes in heroin and
23 illegally manufactured synthetics market?

24 A. Yes.

25 Q. And if you go down, the next

1 paragraph, it says, "The supply side routes of the
2 overdose epidemic in the United States lie at the
3 intersection of two social and behavioral forces
4 that together led to the proliferation of opioid
5 prescribing in the 1990s, especially for noncancer,
6 acute and chronic pain conditions."

7 Did I read that correctly?

8 A. You did.

9 Q. Okay. And so your article is saying
10 there are two forces that combine to lead to an
11 increase in opioid prescribing by physicians,
12 correct?

13 A. The article does not mention by
14 physicians, just prescribing, including dispensing.

15 Q. Well, is it your understanding that
16 CVS -- well, any pharmacy is only supposed to
17 dispense a prescription if they receive a -- well,
18 only supposed to dispense a prescription to a
19 patient if they receive a prescription from a --
20 written by a licensed prescriber?

21 A. That's correct.

22 Q. Okay. So the first step is, there
23 has to be a prescription written by a doctor,
24 correct?

25 A. A first step of what?

1 Q. In order for there to be a
2 proliferation of prescriptions, doctors had to
3 write more prescriptions, correct?

4 A. There were more prescriptions written
5 by doctors in the 1990s.

6 Q. Okay. And the article goes on to
7 say, "The first force was a shift in treatment
8 approaches for chronic noncancer pain, including a
9 campaign by professional societies and the U.S.
10 Joint Commission, the nation's largest accrediting
11 body for healthcare organizations, to consider pain
12 as a fifth vital sign and to improve the quality of
13 care for chronic pain." Did I read that correctly?

14 A. Yes.

15 Q. And then it goes on to say, "In 1997,
16 the American Pain Society and the American Academy
17 of Pain Medicine released a consensus statement
18 endorsing the use of opioids to treat chronic
19 noncancer pain, arguing that the risk of addiction
20 from opioids was low. At the time, the risk of
21 addiction associated with opioid use was not well
22 understood." Did I read that correctly?

23 A. You read that correctly.

24 Q. And so this article that you authored
25 says that the first force that led to increased

1 prescribing was that people began to approach
2 treating pain differently than they had previously,
3 correct?

4 A. Correct.

5 Q. Okay. The medical standard of care
6 for treating pain changed, correct?

7 MR. ARBITBLIT: Objection,
8 speculative. Outside the scope.

9 A. That is not what the article states.

10 Q. (BY MR. HERMAN:) Well, have you
11 yourself said that it became standard practice to
12 use prescription opioids to treat pain?

13 A. Yes.

14 Q. And when you used the term "standard
15 practice," you were talking about standard practice
16 by prescribers to treat pain, correct?

17 A. Are you referring to a specific
18 section of this article or a different article? I
19 just want to make sure I contextualize it
20 appropriately.

21 Q. Well, I am referring -- well, why
22 don't we try to answer it without an article. When
23 you used the term that it became "standard
24 practice" to use prescription opioids to treat
25 pain, would you be referring to standard practice

1 by physicians?

2 MR. ARBITBLIT: Objection. The
3 witness has the right to look at the context.

4 A. I would prefer -- just to make sure I
5 am testifying correctly, I just want to give you
6 the right information. So there are various
7 articles I have written about pain medicine. And
8 so if there's a specific article you would like me
9 to discuss, I would prefer to see it.

10 MR. HERMAN: Can you pull up --

11 Q. (BY MR. HERMAN:) Professor Keyes,
12 can you open Exhibit 12? And Professor Keyes,
13 Exhibit -- well, for this deposition, it is going
14 to be Exhibit 7, I believe.

15 (Exhibit 7 was marked for
16 identification.)

17 Q. (BY MR. HERMAN:) Exhibit 7 is an
18 article that you authored called "Understanding the
19 Rural-Urban Differences in Nonmedical Prescription
20 Opioid Use and Abuse in the United States."

21 A. Sorry. I don't mean to interrupt
22 you. I accidentally opened up the wrong -- this
23 was 7-12, and I accidentally opened it.

24 Q. That is okay. Just set that aside
25 for now.

1 A. Okay. I need to find CVS 12.

2 Q. Okay. Appreciate that.

3 A. I apologize.

4 MS. POLLOCK: Steven, will you be
5 uploading that to Exhibit Share?

6 MR. HERMAN: It is uploading now.

7 MS. POLLOCK: Thank you.

8 THE REPORTER: I don't believe you
9 had an Exhibit 6.

10 MR. HERMAN: I thought --

11 THE REPORTER: Let me refresh and
12 make sure.

13 MR. HERMAN: We may have to get this
14 straightened out, but I thought the last one, what
15 we were talking about, "A Critical Review of the
16 Social and Behavioral Contributions to the Opioid
17 Epidemic," is Exhibit 6.

18 THE REPORTER: Okay. I see that. It
19 is up on Exhibit Share now. Thank you.

20 Q. (BY MR. HERMAN:) Professor Keyes, do
21 you have CVS 12, what is going to be marked as
22 Exhibit 7 for this deposition now?

23 A. I do.

24 Q. Okay. And that is an article titled
25 "Understanding the Rural-Urban Differences in

1 Nonmedical Prescription Opioid Use and Abuse in the
2 United States" that you are an author on that was
3 published in February 2014?

4 A. Yes.

5 Q. And if I could ask you to turn to
6 Page 2 [sic], under the heading, "Self-Medicating
7 for Pain." And do you see where you wrote, "When
8 used as prescribed under medical supervision,
9 opioid analgesics are effective and used as
10 standard practice in managing acute and chronic
11 pain"? Do you see where I am reading?

12 A. I do.

13 Q. Okay. And when you use the term
14 "standard practice in managing acute and chronic
15 pain," were you referring to standard medical
16 practice by physicians?

17 A. Yes.

18 Q. Okay. Do you believe the opioid
19 epidemic would have occurred if prescribing opioids
20 for medical care for treating pain did not become
21 standard practice?

22 MR. ARBITBLIT: Objection.
23 Speculative.

24 A. I think what I have outlined in my
25 report is that there is a constellation of factors

1 that contributed to the opioid epidemic, and one of
2 those factors was the vast increase in the supply
3 of opioids, including through physician
4 prescription.

5 Q. (BY MR. HERMAN:) Well, I am asking
6 you, though, a different question, and I would like
7 you to listen.

8 Do you -- do you believe that the
9 opioid epidemic would have occurred if prescribing
10 opioids did not become standard practice in
11 managing acute and chronic pain?

12 MR. ARBITBLIT: Objection. Asked and
13 answered.

14 A. I do not believe it would have
15 occurred, because it is part of that large
16 constellation of factors that led to oversupply.

17 Q. (BY MR. HERMAN:) You do not believe
18 that the increase in prescribing as standard
19 practice led to the opioid epidemic?

20 MR. ARBITBLIT: Objection. Asked and
21 answered. Misstates the testimony.

22 A. The question was: Do you believe
23 that the opioid epidemic would have occurred if
24 prescribing opioids had not become standard
25 practice? And I believe I answered the question

1 that I do not believe it would have occurred if
2 opioids did not become standard practice, because
3 it led to this oversupply.

4 Q. (BY MR. HERMAN:) But do you believe
5 that the prescribing of opioids for the treatment
6 of pain as standard practice led to the oversupply
7 of prescription opioids?

8 MR. ARBITBLIT: Object to form.

9 A. It was one of the factors that led to
10 oversupply.

11 Q. (BY MR. HERMAN:) Okay. And going
12 back to Exhibit 6, CVS 5 for you, the article says,
13 "The second, related force involved the
14 pharmaceutical industry's concerted effort to
15 advocate for long-term use of opioids as a safe,
16 nonaddictive, effective, and humane alternative to
17 treat noncancer pain. These marketing efforts
18 accelerated the shift in treatment approaches for
19 chronic noncancer pain."

20 Did I read that correctly?

21 A. Yes.

22 Q. Okay. And the example you go on to
23 give in the next few sentences is about Purdue,
24 right?

25 A. Yes.

1 Q. Purdue is a manufacturer, correct?

2 A. That's correct.

3 Q. When you refer to the pharmaceutical
4 industry in this sentence, were you referring to
5 Purdue and other manufacturers?

6 A. I believe several sentences later I
7 define the pharmaceutical industry as including the
8 production, distribution and prescription of
9 opioids proliferated due to the removal of
10 physician sanctions. So the pharmaceutical
11 industry is broadly conceived.

12 Q. Okay. What is your basis for saying
13 that the marketing efforts that accelerated the
14 shift in treatment approaches for chronic noncancer
15 pain was caused by entities other than
16 manufacturers?

17 A. Can you point me to where you are
18 looking?

19 Q. The second force -- so it's at the
20 top of the paragraph, the second force --

21 A. Uh-huh.

22 Q. -- "involved the pharmaceutical
23 industry's concerted efforts to advocate for the
24 long-term use of opioids as safe, nonaddictive,
25 effective, and humane alternative to treat

1 noncancer pain. These marketing efforts
2 accelerated the shift in treatment approaches for
3 chronic noncancer pain."

4 A. Yes, that is what it says.

5 Q. Okay. And -- well -- okay. Well,
6 the only example you give is Purdue, a
7 manufacturer. So I am wondering, what basis do you
8 have to say that other -- any part of the
9 pharmaceutical industry other than manufacturers
10 engaged in marketing efforts that accelerated the
11 shift in treatment approaches for chronic noncancer
12 pain?

13 MR. ARBITBLIT: Object to form.
14 Misstates.

15 A. I guess I am still not understanding
16 the question. The --

17 Q. (BY MR. HERMAN:) Well --

18 A. I say in here that there were
19 "concerted efforts to advocate for the long-term
20 use of opioids as" -- and that those concerted
21 efforts involved the pharmaceutical industry.
22 Several sentences later, I provide context for that
23 statement, saying that -- that the Intractable Pain
24 Act "removed physician sanctions for the use of
25 opioids" and that "the production, distribution,

1 prescription, and use of opioids proliferated."

2 So all entities that would be
3 involved in the production, distribution,
4 prescription and use of opioids would be implicated
5 in that statement.

6 Q. Okay. Well, your report discusses --
7 and going back to Exhibit 1, your report discusses
8 how direct marketing to physicians increased
9 prescribing, correct?

10 MR. ARBITBLIT: Objection. Vague.

11 A. So that section in the report
12 describes three papers that have used data on
13 payments to physicians and associations with
14 various outcomes.

15 Q. (BY MR. HERMAN:) Okay. And on Page
16 14, I think that is where you are talking about,
17 you are discussing how direct marketing to
18 physicians increased prescribing, right, and you
19 cite -- I think you just said three papers for that
20 proposition?

21 A. I am -- I am on Page 14 of the
22 report, but I think it is actually later in the
23 report, just so it is accurate in the record.

24 Q. So you talk about it at Page 14 and
25 then again at Page 33?

1 A. Oh, I see. The marketing -- I state
2 in the -- in the report that the "marketing of
3 opioid drugs led to increased sales of the marketed
4 drugs."

5 Q. Well, you say on Page 14,
6 "Evidence" -- "The increase in opioid prescribing
7 was driven by a multitude of factors, including
8 direct marketing to physicians using data that
9 underestimated opioid use disorder risks in
10 patients, which I detail in Section B. Evidence
11 shows that pharmaceutical marketing of prescription
12 drugs increases prescribers' likelihood of
13 prescribing the marketed drug in the future,"
14 right?

15 A. That is a general statement about
16 prescription drugs and marketing. The next
17 sentence is about opioids.

18 Q. Yeah. "That is also true for
19 prescription opioids; as a result, increased
20 marketing of opioids led to increased sales of the
21 marketed drugs," right? And you cite a couple of
22 studies?

23 A. Correct.

24 Q. The literature that you cite about
25 marketing discusses marketing activities by

1 pharmaceutical manufacturers to physicians,
2 correct?

3 A. Is there a specific study that you
4 are referring to?

5 Q. I am asking about all of them at the
6 moment. The literature that you cite in your
7 report about marketing activities to physicians
8 discusses marketing activities by manufacturers to
9 physicians, correct?

10 A. Are the articles in the exhibits,
11 because I would just like to confirm that that is
12 what the articles state?

13 Q. You don't know off the top of your
14 head whether the articles are discussing marketing
15 activities that pharmaceutical manufacturers engage
16 in?

17 A. There -- the articles refer to a
18 database called the Sunshine Open Payments
19 database, I believe, and I would like to -- I would
20 feel more comfortable giving correct testimony if I
21 could look at the article and make sure that I am
22 describing what is included in the contents of the
23 Open Payments database accurately.

24 Q. Okay. Well, why don't we look at --
25 why don't we try 7 -- did you tell me you already

1 opened 7-12?

2 A. I did open 7-12, yes.

3 MR. HERMAN: Why don't we mark it --
4 mark that as Exhibit 8.

5 (Exhibit 8 was marked for
6 identification.)

7 MR. HERMAN: And --

8 THE VIDEOGRAPHER: Counsel, your
9 screen sharing is in the video.

10 MR. HERMAN: When -- I am sorry. The
11 screen sharing is in the video. Can you see me?

12 THE VIDEOGRAPHER: No, the screen --
13 the screen being shared is in the video. I was
14 just letting him know, whoever was sharing.

15 MR. HERMAN: Oh.

16 Q. (BY MR. HERMAN:) Exhibit 8 is an
17 article titled, "Association of Industry Payments
18 to Physicians with the Prescribing of Brand-name
19 Statins in Massachusetts."

20 A. Yes, that is correct.

21 Q. Okay. And do you see on Page 763 --
22 well, let me ask you this: This is one of the
23 articles you cite in your report, correct?

24 A. Yes, but I don't think it is on -- I
25 don't cite this on Page 14. I believe I cite this

1 in the other section that discusses the Hadland
2 article. So if I could just pull up that section
3 to make sure I am -- is that correct? To make
4 sure -- do you know which number --

5 Q. It -- I believe this is Reference
6 141, so maybe it is --

7 A. Yeah.

8 Q. You cite some of them in both places,
9 but I think this is one cite on Page --

10 A. This is only -- I just wanted to pull
11 up the correct section. Okay.

12 Q. Okay. Do you see on Page 763, it
13 says, "Payment by pharmaceutical manufacturers to
14 physicians outside the research context may be
15 problematic, because they can be perceived as
16 conflicts of interest that could interfere with
17 physicians' responsibilities to their patients"?

18 A. This is on Page 763?

19 Q. Yep, first paragraph.

20 A. Oh, I see. Yes. I see that.

21 Q. You see above it says, "In the United
22 States" -- the paragraph begins, "In the United
23 States, many physicians have financial
24 relationships with pharmaceutical manufacturers."

25 A. I see that.

1 Q. Okay. Did I read that correctly?

2 A. You did.

3 Q. Is it your understanding that this
4 article about payments to physicians relates to
5 manufacturers?

6 A. That this particular article about
7 statins? You are asking -- you are asking
8 whether --

9 Q. Well, I am asking -- this is -- you
10 said you would like to see an article. I am --
11 I -- well, I am asking you, does this article deal
12 with payment by manufacturers?

13 A. This article does -- the methods
14 section of this paper says that they used two data
15 sources. This -- the data source that was used on
16 payments was the Massachusetts physician Open
17 Payments database, which is derived from
18 pharmaceutical manufacturer reports. But the
19 article does not include opioids, as far as I can
20 tell.

21 Q. Okay. I -- well, we are short on
22 time. I'm not sure I am going to be able to go
23 through every article.

24 But sitting here today, do you
25 believe that the literature you cite in your report

1 about marketing to physicians discusses marketing
2 activities by pharmaceutical manufacturers?

3 MR. ARBITBLIT: Object to form.

4 A. I cite a variety of studies. If
5 there's a specific study that you are asking about,
6 I can look at the study and see what was included.

7 Q. (BY MR. HERMAN:) All right. Let's
8 look at 72-26. Oh, I'm sorry. This is 7-2. we
9 will mark that as Exhibit 9.

10 (Exhibit 9 was marked for
11 identification.)

12 A. So it is 7-26?

13 Q. (BY MR. HERMAN:) Well, 7-2, I'm
14 sorry, and it is Reference 26 in your --

15 A. Okay. 7- --

16 Q. -- report. And this is an article
17 entitled, "Association of Pharmaceutical Industry
18 Marketing of Opioid Products to Physicians With
19 Subsequent Opioid Prescribing." Is that correct?

20 A. That is correct.

21 Q. And this is one of the papers you
22 cite in your report at both Page 14 and Page 33?

23 A. Yes.

24 Q. Okay. And this looked at the Open
25 Payments database that you were asking about?

1 A. Yes.

2 Q. And the authors obtained information
3 from the Open Payments database on all transfer of
4 value from pharmaceutical companies to physicians
5 during 2014, right?

6 A. That's correct.

7 Q. Okay. And if you would look at Page
8 862, the "Results" column, do you see where it
9 says, "The three companies with the highest payment
10 totals were INSYS Therapeutics (which manufactures
11 Subsys, the fentanyl sublingual spray), Teva
12 Pharmaceuticals USA, and Janssen Pharmaceuticals"?

13 A. I see that.

14 Q. Okay. And do you understand that
15 INSYS, Teva and Janssen are all manufacturers?

16 A. I do understand that.

17 Q. And if you turn to Page 863, do you
18 see the first full paragraph, where it says, "Our
19 findings add to prior studies of industry marketing
20 to physicians by examining" -- oh, sorry. Strike
21 that.

22 Do you see the last paragraph? After
23 the introductory clause, it says, "our findings
24 suggest that manufacturers should consider a
25 voluntary decrease or complete cessation of

1 marketing to physicians"?

2 MR. ARBITBLIT: Object to reading a
3 partial sentence.

4 MR. HERMAN: Okay. I will read the
5 full sentence.

6 Q. (BY MR. HERMAN:) "Amidst national
7 efforts to curb the overprescribing of opioids, our
8 findings suggest that manufacturers should consider
9 a voluntary decrease or complete cessation of
10 marketing to physicians." Did I read that
11 correctly?

12 A. You did.

13 Q. Okay. And is it your understanding
14 that this article relates to marketing by
15 manufacturers?

16 A. My understanding is that the data
17 source as described in the Methods section says
18 "pharmaceutical companies."

19 Q. Well, do you have an understanding --

20 A. The three top companies that you
21 cited were three opioid manufacturers, but I have
22 not looked into the Open Payments database in
23 enough detail to know that every company included
24 in the Open -- Open Payments database is a
25 manufacturer.

1 Q. Sorry. So you don't know -- I mean,
2 the recommendation certainly is about
3 manufacturers, correct?

4 A. In -- in the Discussion section, it
5 says there's a national effort to curb
6 overprescribing and that one way to do that would
7 be to suggest manufacturers cease marketing to
8 physicians.

9 Q. Okay.

10 A. It does not preclude other efforts.

11 Q. Tell me everything you know about
12 marketing by pharmacies.

13 MR. ARBITBLIT: Object to form.
14 Vague. Overbroad.

15 A. Everything I know about -- if there's
16 a specific document that you would like me to
17 review, I can -- I can do that. Otherwise, I would
18 prefer to stick to what is in my report.

19 Q. (BY MR. HERMAN:) Okay.

20 A. In terms of my general knowledge
21 about marketing by pharmacies, pharmacies market
22 all kinds of products.

23 Q. Do you know if any of these studies
24 apply to pharmacies?

25 MR. ARBITBLIT: Objection. Vague.

1 A. I believe what I have testified is
2 that what is written in the Methods section of this
3 Hadland article is that the Open Payments database
4 includes information from pharmaceutical companies.
5 And I have not looked at every company that is in
6 the Open Payments database. And that's as much
7 information as I can -- I can give.

8 Q. (BY MR. HERMAN:) Sitting here today,
9 do you know if any of the opinions you are giving
10 about marketing are applicable to pharmacies?

11 MR. ARBITBLIT: Objection. Vague.
12 Overbroad.

13 A. I think all of the opinions that I
14 have given are applicable to all -- they are --
15 they are -- they are -- the opinions are what they
16 are. And they are applicable -- for example, I say
17 that there is overprescribing and oversupply. I
18 think that certainly applies to pharmacies.

19 Q. (BY MR. HERMAN:) Okay. Sticking to
20 marketing, I asked specifically about whether your
21 opinions -- whether any of these studies about
22 marketing relate to pharmacies.

23 MR. ARBITBLIT: Objection. Vague,
24 interrupted the witness and misstates the prior
25 question.

1 A. I think what I have written here is
2 the amount of information that I have, which is
3 that these articles apply to pharmaceutical company
4 marketing. And I would have to look at the extent
5 to which -- I don't know what companies are -- the
6 totality of companies that are included in the Open
7 Payments database.

8 Q. (BY MR. HERMAN:) So in the course of
9 your work, you haven't analyzed the materials in
10 your report to determine who is marketing? That is
11 your testimony?

12 MR. ARBITBLIT: Object to the form.
13 Argumentative.

14 A. Determine who is marketing? I don't
15 know what you mean by "who is marketing."

16 Q. (BY MR. HERMAN:) Well, in the course
17 of your work, you are offering opinions about
18 marketing. In this report, you haven't analyzed
19 the materials that you cite in your report to
20 determine who is engaged in marketing?

21 MR. ARBITBLIT: Object to form.
22 Vague. Overbroad.

23 Q. (BY MR. HERMAN:) True or false?

24 A. I have reviewed the epidemiological
25 evidence and reported it in this report to the best

1 of my ability. And what I reported is that
2 pharmaceutical companies are in the Open Payments
3 database.

4 Q. But you don't know what
5 "pharmaceutical companies" actually refers to, and
6 you would agree with me that this article only
7 discusses manufacturers, correct?

8 MR. ARBITBLIT: Objection. Compound.

9 A. What I can testify is that, in the
10 Results section of this paper, three companies are
11 mentioned, and those three companies are
12 manufacturers.

13 Q. (BY MR. HERMAN:) And in the
14 recommendation that the study makes at the end, it
15 only mentions manufacturers, correct?

16 MR. ARBITBLIT: Objection. Misstates
17 the record.

18 A. No, that is not correct. The
19 sentence says that there are national efforts to
20 curb overprescribing, which is not specific to
21 manufacturers. And the second part of the sentence
22 suggests that manufacturers curb marketing to
23 physicians.

24 Q. (BY MR. HERMAN:) In an article about
25 marketing to physicians, their "findings suggest

1 that manufacturers should consider a voluntary
2 decrease or complete cessation of marketing to
3 physicians." You don't agree that is only about
4 manufacturers?

5 MR. ARBITBLIT: Object to form.
6 Argumentative. Misstates the record.

7 A. I think I would consider the whole
8 sentence together, which starts, "Amid national
9 efforts to curb the overprescribing of opioids."
10 And I think that that is a more general statement.

11 Q. (BY MR. HERMAN:) Okay. You don't --
12 you don't agree with me that this article that
13 cites manufacturers, three manufacturers as the
14 largest payors and then makes a recommendation only
15 as to manufacturers is about manufacturers?

16 MR. ARBITBLIT: Objection. Asked and
17 answered. Compound. Argumentative.

18 A. I think that is a narrow
19 interpretation of the data.

20 Q. (BY MR. HERMAN:) Okay. You actually
21 don't know, as you previously testified, what the
22 data in the Open Source Payment reflects, correct?

23 MR. ARBITBLIT: Objection. Asked and
24 answered.

25 A. I have -- sorry. I have not reviewed

1 every company that is in the Open Payments
2 database.

3 Q. (BY MR. HERMAN:) Have you reviewed
4 any companies?

5 A. I have reviewed the epidemiological
6 literature, of which this article is one of
7 several, and reported its results faithfully.

8 Q. Okay. So you made no effort to
9 identify who was responsible for the marketing of
10 opioids?

11 MR. ARBITBLIT: Object to form.
12 Misstates the record. Argumentative.

13 A. The effort that I made was to review
14 the evidence and report it, and that is what I have
15 done in my report.

16 Q. (BY MR. HERMAN:) Well, tell me
17 everything you know about pharmacies' marketing of
18 prescription opioids.

19 MR. ARBITBLIT: Objection.
20 Previously asked. Argumentative. Overbroad.
21 Vague.

22 A. In my report, I discuss various
23 marketing efforts, as they have been reported in
24 the epidemiological literature. I'm not offering
25 opinions about specific companies' marketing, as I

1 note in the report.

2 Q. (BY MR. HERMAN:) You don't know --
3 you don't know which companies engaged in which
4 activities, if any at all, correct?

5 MR. ARBITBLIT: Objection. Vague.

6 A. I am not offering -- I -- in terms of
7 what is reported in these articles, there are
8 specific companies mentioned. And so to the extent
9 that specific companies are mentioned in the
10 epidemiological literature, that is what I feel
11 like I have the expertise to report on.

12 But I am not offering opinions about
13 specific pharmacy marketing.

14 Q. (BY MR. HERMAN:) All those companies
15 that are specifically mentioned are manufacturers,
16 correct?

17 A. The three companies mentioned in
18 Hadland's 2018 are manufacturers.

19 Q. I meant -- I am -- I am talking in
20 any article. Like we just looked at one where you
21 discussed Purdue, correct? That is a manufacturer.

22 MR. ARBITBLIT: Object to form.
23 Compound. Vague.

24 A. I would not offer testimony about
25 every article. I can speak to each article at the

1 time.

2 Q. (BY MR. HERMAN:) Did you review
3 those articles carefully before using them in your
4 report?

5 A. I did.

6 Q. Do you recall any mention of
7 marketing by pharmacies?

8 MR. ARBITBLIT: Object to form.

9 A. I would need to review each article
10 again.

11 Q. (BY MR. HERMAN:) Okay. So sitting
12 here today, you don't know what companies engaged
13 in marketing activity?

14 MR. ARBITBLIT: Object to form.

15 A. Sitting here today, I can report on
16 the companies that are specifically mentioned in
17 these articles.

18 Q. (BY MR. HERMAN:) And those are all
19 manufacturers?

20 MR. ARBITBLIT: Object to form.

21 Asked and answered. Overbroad.

22 A. The company -- the three companies
23 that I mentioned in Hadland 2018 are manufacturers.
24 And we can look at the other Hadland articles to go
25 through the companies that are mentioned in those

1 as well.

2 Q. (BY MR. HERMAN:) And the marketing
3 activities that -- the studies you are looking at
4 are marketing to prescribers, correct?

5 A. They are marketing to physicians.

6 Q. Okay. And when you are talking about
7 factors that led to increased prescribing, you are
8 speaking about the general population of
9 prescribers, not specific prescribers, correct?

10 A. There is information on specific
11 types of prescribers in various articles, but there
12 was an overall increase in opioid prescriptions
13 across many different types of prescribers, I
14 guess. If that -- if I am -- I might be
15 misunderstanding the question, so I am sorry if I
16 am.

17 Q. I will try to do it a little
18 differently.

19 You don't know what caused a
20 particular prescriber to write a particular
21 prescription, correct?

22 MR. ARBITBLIT: Object to form.

23 A. I have not evaluated particular
24 prescribers.

25 Q. (BY MR. HERMAN:) Okay. You don't

1 know a particular prescriber's knowledge about the
2 potential risks of prescription opioids, correct?

3 MR. ARBITBLIT: Object to form.

4 A. I can -- I can speak in generalities
5 about what the epidemiological literature says
6 about prescribers, but I have not evaluated any
7 singular prescriber.

8 Q. (BY MR. HERMAN:) You don't know
9 whether a particular prescriber saw marketing
10 materials, correct?

11 A. I don't have any -- I don't have any
12 expertise on particular prescriber, so I do not
13 know whether they saw marketing materials.

14 Q. Okay. And I think you have already
15 answered this, but you don't know what, if any,
16 marketing materials doctors who prescribed opioids
17 in Trumbull and Lake Counties saw, correct?

18 A. That's correct.

19 Q. Okay. Can I ask you to turn to Page
20 40 of your report? And can you see at the end of
21 the first full paragraph where there's a reference
22 to "'aggressive and highly'" -- it is a quote,
23 "'aggressive and highly effective marketing tactics
24 on the part of the pharmaceutical industry
25 (manufacturers, distributors and pharmacies)'"?

1 A. Yes, I see that.

2 Q. And you cite to Reference 190 and
3 specifically Section 719 for that proposition.

4 A. Yes.

5 Q. Okay.

6 (Exhibit 10 was marked for
7 identification.)

8 MR. HERMAN: Can -- Jason, can we
9 pull up -- what exhibit are we on, 9?

10 MR. ACTON: Yeah.

11 Q. (BY MR. HERMAN:) Can I ask you to
12 open Exhibit -- CVS Exhibit 6, Professor Keyes?
13 And Exhibit 9 [sic] is a document called "High and
14 Rising Mortality Rates Among Working-Aged Adults."
15 And is that what you referenced as Reference 190 in
16 your report?

17 A. It is.

18 Q. Okay. And if I could ask you to turn
19 to 7-19. And do you see where you pulled that
20 quote from, there's a citation in support of it to
21 an article by Kolodny, et al., 2015?

22 A. Page 7-19.

23 Q. Do you see at the top it says --

24 A. Oh, I was looking in the wrong
25 section.

1 Q. Quoted at the top, "Aggressive and
2 highly effective marketing tactics on the part of
3 pharmaceutical industry (manufacturers,
4 distributors, pharmacies)." And there's a citation
5 to Kolodny et al. --

6 A. Yes.

7 Q. -- in support of that. Okay.

8 MR. HERMAN: Can I ask you, Jason, to
9 pull up Exhibit 10 -- well, it's going to be
10 Exhibit 10 --

11 MR. ACTON: 11.

12 Q. (BY MR. HERMAN:) Oh, Exhibit 11.
13 And, Professor Keyes, can I ask you to open
14 Exhibit -- CVS Exhibit 8?

15 A. I'm sorry. I -- the Kolodny article
16 is citing actions of the legal and illegal drug
17 suppliers and regulatory failures of government
18 agencies.

19 Q. Well, I believe, though, it is also
20 the only citation in support of "aggressive and
21 highly effective marketing tactics on the part of
22 the pharmaceutical industry (manufacturers,
23 distributors, and pharmacies)"?

24 A. Oh, I see. In the second paragraph.

25 Q. Yeah. Okay.

1 A. Okay.

2 MR. HERMAN: Can we pull up that
3 Kolodny article, if you could open CVS 8? And that
4 is going to be Exhibit 11.

5 (Exhibit 11 was marked for
6 identification.)

7 A. CVS 7-8 or CVS 8?

8 Q. (BY MR. HERMAN:) CVS 8.

9 A. Okay.

10 Q. Okay. And CVS 8 is an article
11 entitled "The Prescription Opioid and Heroin
12 Crisis: A Public Health Approach to an Epidemic of
13 Addiction," and the authors are Andrew Kolodny,
14 David T. Courtwright, Katherine Hwang, Peter
15 Kreiner, John L. Eadie, Thomas W. Clark, and G.
16 Caleb Alexander, and this was an article published
17 January 12th, 2015; is that correct?

18 A. Yes.

19 Q. Okay. Are you aware that Professor
20 Alexander has been retained by and identified as an
21 expert witness by plaintiffs in this opioid
22 litigation?

23 MR. ARBITBLIT: Object to form.
24 Vague as to time.

25 A. Could you specify what you mean by

1 "this opioid litigation"?

2 Q. (BY MR. HERMAN:) Well, in the case
3 that you are here testifying in today, the Trumbull
4 and Lake County case.

5 MR. ARBITBLIT: Same objection.

6 A. I have -- I have been vaguely aware
7 that Dr. Alexander has been -- I think I have
8 supplied him with some estimates. And that is my
9 knowledge of his involvement.

10 Q. (BY MR. HERMAN:) Okay. So as part
11 of your work with the plaintiffs, you have provided
12 Dr. Alexander estimates?

13 A. Yes.

14 Q. Okay. Are you aware that Professors
15 Courtwright and Kolodny have been retained by and
16 identified as expert witnesses by plaintiffs in
17 other opioid litigation cases?

18 MR. ARBITBLIT: Same objection.
19 Vague as to time. Misleading.

20 A. I have seen Dr. Kolodny's name in
21 other litigation, and I don't recall seeing
22 Dr. Courtwright.

23 Q. (BY MR. HERMAN:) Okay. Okay. And
24 if I direct your attention to, "In addition to
25 minimizing risks of OPRs, the campaign" -- well, I

1 direct your attention to 562, the bottom of the
2 page. Do you see where it says, "In addition to
3 minimizing the risks of OPRs, the campaign advanced
4 by opioid manufacturers and pain organizations
5 exaggerated the benefits of long-term opioid use"?
6 Do you see that?

7 A. "In" -- yeah, "the campaign advanced
8 by opioid manufacturers and pain organizations" --
9 yes, I see it.

10 Q. Okay. And that only discusses opioid
11 manufacturers, correct?

12 MR. ARBITBLIT: Object to form.
13 Misstates.

14 A. That sentence refers to "opioid
15 manufacturers and pain organizations."

16 Q. (BY MR. HERMAN:) Well, okay. Does
17 it discuss pharmacies?

18 A. That particular sentence or the
19 article?

20 Q. Well, before quoting "High and Rising
21 Mortality Rates Among Working-Age Adults" about
22 aggressive and effective -- or marketing by
23 manufacturers, distributors and pharmacies, did you
24 look to see whether it or the article it cited
25 provided any support for the idea that pharmacies

1 engaged in, quote/unquote, aggressive and effective
2 marketing of prescription opioids?

3 MR. ARBITBLIT: Object to form.
4 Argumentative.

5 A. Yes.

6 Q. (BY MR. HERMAN:) Okay. Tell me what
7 in either of those discusses marketing by
8 pharmacies.

9 MR. ARBITBLIT: Object to form.

10 A. In that sentence or the whole
11 article?

12 Q. (BY MR. HERMAN:) Well, you said you
13 checked. So if you could point me to where there's
14 discussion of marketing by pharmacies, I would ask
15 that you do so.

16 MR. ARBITBLIT: Object to form.
17 Argumentative.

18 A. I'm not sure where -- I can read the
19 article again.

20 Q. (BY MR. HERMAN:) Well, tell me
21 everything -- I have asked you a couple of times
22 now. I have asked you to tell me everything you
23 know about marketing by pharmacies from this
24 article or otherwise, and I haven't gotten a
25 response.

1 MR. ARBITBLIT: Object to form.
2 Argumentative. Misstates.

3 A. Yeah, I mean, just glancing over this
4 article, it mentions opioid companies a number of
5 times.

6 Q. (BY MR. HERMAN:) Do you know if
7 those companies are pharmacies?

8 MR. ARBITBLIT: Object to form.
9 Interrupting the witness.

10 A. I don't see specific pharmacies
11 mentioned in this article. But there is discussion
12 of a range of opioid companies, or companies that
13 are involved in the distribution of opioids. And
14 this article, as well as many others, have
15 discussed the distribution of opioids as part of an
16 oversupply problem.

17 Q. (BY MR. HERMAN:) Okay. Where does
18 it discuss marketing -- I mean, you're -- it seems
19 to me that you are changing the question. But
20 where does it discuss marketing by pharmacies to
21 support the idea that pharmacies engaged in
22 aggressive and effective marketing?

23 MR. ARBITBLIT: Object to the form.
24 Argumentative.

25 A. I -- so the sentence that is cited

1 with regard to the National Academies report is
2 broader than just marketing activities. It
3 includes flooding the market with highly addictive,
4 yet deadly substances. And I think that the
5 Kolodny article provides pretty solid evidence of
6 the flooding of the market --

7 Q. (BY MR. HERMAN:) Well, that -- go
8 ahead.

9 A. -- so it is an appropriate citation
10 for that sentence.

11 Q. Well, if you're talking --

12 A. With regard to specific marketing
13 activities, no specific marketing activities are
14 discussed in this article, but a broad range of
15 activities by these companies is discussed in the
16 article. And there's discussion of marketing by
17 various companies.

18 Q. But you would agree with me, I mean
19 the sentence that you quote in your report is, "On
20 the supply side, weak government regulations and
21 aggressive and highly effective marketing tactics
22 on the part of the pharmaceutical industry
23 (manufacturers, distributors, pharmacies)," that
24 neither of these sources provide support for the
25 ideas that pharmacies engaged in aggressive and

1 highly effective marketing?

2 MR. ARBITBLIT: Object to form.

3 A. That -- the citation of the Kolodny
4 article is a -- is a larger sentence. It is -- it
5 is not just the --

6 Q. (BY MR. HERMAN:) Well, but I am
7 asking you about the portion of the sentence that
8 says "aggressive and highly effective marketing."
9 You would agree with me that the Kolodny article
10 does not provide support for the idea that the
11 pharmacies engaged in highly effective and
12 aggressive marketing, correct?

13 A. I would not agree with that broad of
14 a statement.

15 Q. Well, what is your basis that the
16 pharmacies engaged in aggressive and highly
17 effective marketing?

18 A. My testimony is that the Kolodny
19 article describes overall industry marketing and
20 distribution practices that were deceptive and that
21 the pharmacies would be included in that.

22 Q. Well, let's limit it to marketing.
23 We will put aside your editorializing about
24 distribution. But what -- I mean, the marketing
25 example discussed, again, is Purdue. The only

1 campaign advance discussed is by opioid
2 manufacturers and pain organizations. What are you
3 basing your assertion that pharmacies engaged in --
4 that the Kolodny article discusses the fact that
5 pharmacies engaged in any marketing, let alone
6 aggressive and highly effective marketing?

7 MR. ARBITBLIT: Objection. Vague.
8 Argumentative.

9 A. My testimony is the same as the
10 previous question. I think, in citing the Kolodny
11 article, there is discussion of a broad range of
12 activities by companies.

13 Q. (BY MR. HERMAN:) Well, what --

14 A. And that is my -- that is the
15 expertise that I am offering.

16 Q. Okay. But I want to zero in on the
17 marketing aspect. I am only asking you about the
18 activity of marketing.

19 A. Can you define what you mean by
20 "marketing"?

21 Q. Well, what did you mean by it when
22 you used it in your report and you cited this
23 sentence in your report?

24 A. I -- what I meant by "marketing" is
25 activities that increased the oversupply and

1 overprescription of opioids.

2 Q. Okay. And, I mean, when you are
3 talking about marketing to physicians, what
4 marketing activities were you aware of, if any,
5 engaged in by pharmacies?

6 MR. ARBITBLIT: Object to form.

7 A. Neither the report, the National
8 Academies article, or the Kolodny article specifies
9 marketing to physicians when talking about
10 marketing.

11 Q. (BY MR. HERMAN:) But your report --

12 A. That is a separate issue.

13 Q. I mean -- okay. Well, let's just
14 talk about marketing generally. Are you redefining
15 "marketing" to mean distribution, dispensing? Are
16 you including those in marketing now?

17 I mean, I think "marketing" has a
18 pretty -- I mean, what do you mean by "marketing"?

19 MR. ARBITBLIT: Object to form.
20 Compound. Confusing. Vague.

21 A. Yeah, I am not -- what is the
22 specific question?

23 Q. (BY MR. HERMAN:) Let's start on Page
24 14, "direct marketing to physicians." Are you
25 aware of any activities by pharmacies that entail

1 direct marketing to physicians?

2 MR. ARBITBLIT: Object to the form.

3 A. Page 14 of my report?

4 Q. (BY MR. HERMAN:) Yes.

5 MR. ARBITBLIT: Object to form.

6 A. That goes back to the Hadland article
7 and the testimony I have already provided about the
8 Open Payments database.

9 Q. (BY MR. HERMAN:) Okay. So -- and
10 your testimony was you don't know one way or
11 another whether that relates to pharmacies?

12 MR. ARBITBLIT: Object to form.

13 A. We can go back and read the
14 testimony. I mean, I didn't say I don't know one
15 way or the other. What I said was that the Hadland
16 article is based on the Open Payments databases,
17 and that what is reported in the Methods section is
18 that pharmaceutical companies are in the Open
19 Payments database. I have not analyzed the Open
20 Payments database to derive what industry each
21 company that is in the Open Payments database is
22 from.

23 Q. (BY MR. HERMAN:) Okay. And then on
24 Page 33 it says, "exposure to pharmaceutical
25 marketing" -- Page 33 of your report, "exposure to

1 pharmaceutical marketing and sales efforts" --
2 or -- it says, "association between exposure to
3 pharmaceutical marketing and sales efforts with
4 changes in prescribing." And do you know --

5 A. I mean, pharmacies are involved in
6 opioid sales, are they not?

7 MR. ARBITBLIT: Wait for a question.

8 A. Sorry.

9 Q. (BY MR. HERMAN:) Well, I think it is
10 talking about sales efforts with changing in
11 prescriber behaviors, and that is what the studies
12 you cite are about. So are you aware of
13 pharmaceutical marketing efforts and sales efforts
14 that change prescriber behavior that pharmacies
15 engaged in?

16 MR. ARBITBLIT: Object to form.

17 A. Again, this -- I think the articles
18 that are cited there refer to the Open Payments
19 database. So my testimony would be the same, that
20 the Open Payments database, from my understanding,
21 includes pharmaceutical companies, and I am not --
22 I don't know all of the companies that are included
23 in the database.

24 Q. (BY MR. HERMAN:) Okay. So sitting
25 here today, you couldn't give an opinion one way or

1 another whether this relates to your opinions about
2 marketing on Page 14 and Page 33 of your report
3 relate to pharmacies?

4 A. I am not offering opinions about
5 specific marketing activities of specific
6 pharmacies or pharmacy chains. I am offering
7 opinions about these articles in generality, in
8 aggregate.

9 Q. Do you know if CVS engaged in any
10 direct marketing activities to prescribers?

11 MR. ARBITBLIT: Objection. Vague.

12 A. Again, I am not offering opinions
13 about CVS's marketing activities in --
14 specifically.

15 Q. (BY MR. HERMAN:) Okay. So that same
16 answer would apply to Walmart, Walgreens, Rite Aid
17 and Giant Eagle?

18 A. Yes.

19 MR. HERMAN: Okay. We have been
20 going about an hour. Do people want to take a
21 break?

22 A. Sure.

23 MR. ARBITBLIT: All right. We will
24 break for like five minutes.

25 THE VIDEOGRAPHER: Stand by. We are

1 now off the record. The time on the video monitor
2 is 1:52.

3 (Whereupon, a break was had from 1:52
4 p.m. until 2:01 p.m. EDT)

5 THE VIDEOGRAPHER: Stand by. We are
6 now on the record. The time on the video monitor
7 is 2:01.

8 Q. (BY MR. HERMAN:) Dr. Keyes, can I
9 ask you to open 7-27, which will be Exhibit 12 for
10 purposes of this deposition?

11 (Exhibit 12 was marked for
12 identification.)

13 Q. (BY MR. HERMAN:) And do you have
14 that, Doctor, please?

15 A. I am just opening it. The tape is --

16 Q. I saw you struggling a little bit.
17 That is when I realized you didn't have it open.

18 Okay. Do you have it now?

19 A. I do.

20 Q. Okay. And so Exhibit 12 is an
21 article entitled "Patterns of major depression and
22 nonmedical use of prescription opioids in the
23 United States." And you are one of the authors on
24 this article, correct?

25 A. Yes.

1 Q. This was an article published in
2 August 2015?

3 A. Yes.

4 Q. And can I direct your attention to
5 Page 6, the last paragraph? And this article found
6 that "Past-year drug use other than NMUPO and
7 alcohol use disorder were the strongest factors
8 associated with NMUPO alone, MDE alone and NMUPO
9 plus MDE." That is what is read in here, correct?

10 A. Yes.

11 Q. And NMUPO means nonmedical
12 prescription opioid use?

13 A. Nonmedical use of prescription
14 opioids.

15 Q. And MDE means major depressive
16 episode?

17 A. Yes.

18 Q. And can I direct your attention to
19 Table 12 -- or Table 2? I apologize. And
20 directing your attention to the section on
21 adolescents, this table shows that adolescents who
22 had any drug use other than nonmedical use of
23 prescription opioids were 7.9 times more likely to
24 have nonmedical use of prescription opioids alone,
25 correct?

1 A. Let me just familiarize myself. Yes.
2 Past any drug use other than nonmedical use of
3 prescription opioids was associated with eight
4 times higher odds of using prescription opioids
5 nonmedically.

6 Q. Okay.

7 A. Without MDE.

8 Q. Okay. And adolescents who had any
9 drug use other than nonmedical use of prescription
10 opioids were 12.4 times more likely to have
11 nonmedical use of prescription opioids and MDE?

12 A. That's correct.

13 Q. And adults who had any drug use other
14 than nonmedical use of prescription opioids were
15 6.6 times more likely to have nonmedical use of
16 prescription opioids alone, correct?

17 A. That's right.

18 Q. And adults who had any drug use other
19 than nonmedical use of prescription opioids were
20 15.9 times more likely to have nonmedical use of
21 prescription opioids and major depressive episodes?

22 A. Yes.

23 Q. You can set that aside. Can I ask
24 you to open CVS 9? And this will be Exhibit 13.

25 (Exhibit 13 was marked for

1 identification.)

2 Q. (BY MR. HERMAN:) Sorry. I lost --
3 let me know when you have that open.

4 A. I do.

5 Q. And this is an article entitled
6 "Psychoactive substance use prior to the
7 development of iatrogenic opioid abuse: A
8 descriptive analysis of treatment seeking opioid
9 abusers," correct?

10 A. Yes.

11 Q. It is an article by Thomas Cicero and
12 some other authors?

13 A. Theodore, but yes.

14 Q. Oh, that is. Thank you. Theodore
15 Cicero. And if you look at the abstract, it says,
16 "Physicians are frequently thought to be major --
17 be a major source of opioids diverted for
18 nontherapeutic purposes, largely because it is so
19 difficult for them to discern when patients --
20 which patients might abuse them.

21 "In this study, we sought to
22 determine whether those who were first exposed to
23 opioids through a physician's prescription and
24 subsequently developed a substance use disorder had
25 a history of using psychoactive drugs prior to

1 abusing opioids." Correct?

2 A. Yes.

3 Q. And if you look at the introduction,
4 it says, "Healthcare professionals who write opioid
5 prescriptions for acute and, particularly, chronic
6 pain have to consistently balance two often nagging
7 considerations. First, since there is no tool to
8 precisely gauge the presence or severity of the
9 highly subjective experience of pain, physicians
10 must exercise their professional judgment as to
11 whether opioids are warranted or appropriate.

12 "And, second, the more troubling
13 point is it is very difficult for physicians to
14 determine which patients are currently abusing
15 opioids or are at risk for abuse."

16 Did I read that correctly?

17 A. You did.

18 Q. And do you agree with the statements
19 in this introduction that physicians have to
20 consistently balance the two often nagging
21 considerations that are discussed here?

22 MR. ARBITBLIT: Object to form,
23 vague.

24 A. I would agree that these are two
25 among many considerations that healthcare

1 professionals need to make.

2 Q. (BY MR. HERMAN:) And do you agree
3 that the presence or severity -- the determination
4 of the presence or severity of pain is a highly
5 subjective determination?

6 A. Yes, I agree.

7 Q. And do you agree that it is difficult
8 for physicians to determine which patients are
9 currently abusing opioids or are at risk for abuse?

10 A. I wouldn't say that as a blanket
11 statement. Sometimes it can be difficult, and
12 sometimes it is not difficult.

13 Q. And can I ask you to turn to Page 2,
14 "Discussions and Conclusions"? And do you see
15 where it says, "The results of this study indicate
16 that only four percent of those who experienced
17 their first opioid via physician's prescription
18 were truly drug naïve.

19 "Rather, more than ninety-five
20 percent had significant psychoactive drug
21 experience prior to being prescribed their first
22 opioid, a drug with well established mood altering
23 effects.

24 "Two aspects of the data seem
25 noteworthy. First, while nearly our entire sample

1 had used alcohol, nicotine and marijuana before
2 their initial opioid prescription, seventy percent
3 had experience with other types of drugs. And
4 second, on average, four to five different types of
5 drugs were used prior to initial opioid exposure
6 from a prescription"?

7 Do you see that?

8 A. I see that.

9 Q. Did I read that correctly?

10 A. You read it correctly.

11 Q. Any reason you would not expect these
12 figures to apply to individuals prescribed
13 prescription opioids in Lake and Trumbull County?

14 MR. ARBITBLIT: Object to form.
15 Vague. Overbroad.

16 A. Yes. This is not a general
17 population sample. These are people in treatment
18 for prescription opioid use disorders. So these
19 results would not apply to the general population
20 of Lake and Trumbull County.

21 Q. (BY MR. HERMAN:) Would you believe
22 they would apply to the people in need of treatment
23 for opioids in Lake and Trumbull County?

24 MR. ARBITBLIT: Object to form.

25 A. That is not what this sample is.

1 This sample is individuals who are in treatment.

2 Q. (BY MR. HERMAN:) Patients entering
3 one of one hundred and twenty-five drug treatment
4 programs across the country for opioid abuse were
5 asked to provide detailed history, is that what you
6 were referring to, was people entering into
7 treatment?

8 A. Right.

9 Q. Okay. And so that is a population of
10 people who are in need of treatment, correct?

11 MR. ARBITBLIT: Object to form.

12 A. They are people who are in treatment.
13 There are people who are in need of treatment or
14 not in treatment. So it wouldn't comprise the
15 entire population of people who need treatment.

16 Q. (BY MR. HERMAN:) But you would agree
17 with me that it would comprise a subset of the
18 population in need of treatment that is seeking
19 treatment at that time, correct?

20 A. I don't understand the question.

21 Q. Well, let me ask it this way: People
22 in treatment are a subset of the total population
23 of people who need treatment, correct?

24 A. Yes.

25 Q. And so do you have any reason to

1 believe that these statistics for a population in
2 treatment would not generalize to the population in
3 need of treatment?

4 MR. ARBITBLIT: Object to form.

5 A. I have not analyzed that data. I
6 don't know whether these results generalized all
7 those who are in need of treatment.

8 Q. (BY MR. HERMAN:) Well, do you
9 believe that a very small percentage of people who
10 experience their first opioid via physician
11 prescription are truly drug naïve?

12 MR. ARBITBLIT: Object to form.
13 Misstates the record.

14 MR. HERMAN: Well, let me strike
15 that.

16 Q. (BY MR. HERMAN:) This study found
17 the results of this study indicate that only four
18 percent of those who experienced their first opioid
19 via physician's prescription were truly drug naïve,
20 correct?

21 MR. ARBITBLIT: Object to form.

22 A. Those are the results of the study.

23 Q. (BY MR. HERMAN:) And so do you
24 believe that those people who experienced their
25 first opioid via physician prescription who end up

1 needing treatment are truly drug naïve?

2 MR. ARBITBLIT: Object to form.

3 Misstates the record.

4 A. That question is not what this study
5 analyzed.

6 Q. (BY MR. HERMAN:) That is what this
7 study found, correct?

8 MR. ARBITBLIT: Object to form.

9 Misstates the record.

10 A. No, it is not what the study found.
11 The study found that among this population of
12 people in treatment in -- from 2010 to 2015, four
13 percent of those who experienced their first opioid
14 via physician's prescription had not used one of
15 the drugs that were assessed in this study.

16 THE REPORTER: That were what in this
17 study?

18 A. Had not used one of the drugs that
19 were assessed in this study.

20 Q. (BY MR. HERMAN:) Do you have any
21 reason to believe that the patient population that
22 ends up needing treatment who experienced their
23 first opioid via physician's prescription were
24 truly drug naïve?

25 MR. ARBITBLIT: Objection, vague.

1 A. Yes.

2 Q. (BY MR. HERMAN:) What is your basis
3 for saying that the patient population that ends up
4 needing treatment who experience their first
5 prescription opioid through a physician
6 prescription was truly drug naïve?

7 A. This study concludes that four
8 percent who experience their first opioid via a
9 physician's prescription had not used one of the
10 drugs that were assessed in this study. Given the
11 millions of people who have their first opioid,
12 among those who end up going to treatment, four
13 percent is a lot of people.

14 Q. Well, are you agreeing, though, that
15 the four percent would generalize to the population
16 of people who need treatment for --

17 A. I would need to evaluate --

18 THE REPORTER: I'm sorry. Y'all
19 spoke over each other. I couldn't --

20 A. I apologize. I interrupted.

21 Q. (BY MR. HERMAN:) Putting aside
22 whether four percent of the population is a lot of
23 people, do you believe that the four percent figure
24 in this study would be generalizable to the
25 population that ends up needing treatment?

1 MR. ARBITBLIT: Object to form.
2 Speculative.

3 A. I would prefer more study. I mean,
4 generalizing from one study is not typically what
5 we do in epidemiology.

6 Q. (BY MR. HERMAN:) Okay.

7 A. So to evaluate the generalizability
8 of this number, I would need to know what
9 population we are generalizing to, what information
10 we have about their demographic characteristics,
11 that you would just need to consider all of those
12 factors.

13 Q. And you don't know one way or another
14 whether the people in Lake and Trumbull County who
15 might need treatment who experienced their first
16 opioid via a physician's prescription were truly
17 drug naïve?

18 MR. ARBITBLIT: Object to form.

19 A. The people in this study were in
20 treatment, not might need treatment. And the
21 extent to which the four percent would generalize
22 to Lake and Trumbull County, I would need -- I
23 would need further information to evaluate the
24 generalizability.

25 Q. (BY MR. HERMAN:) You can't --

1 whether this study numbers would apply to Lake and
2 Trumbull County, you would need to know -- am I
3 understanding it correctly you would need to know
4 more about the population and characteristics of
5 the people in Lake and Trumbull County?

6 MR. ARBITBLIT: Objection.

7 A. Those who are in treatment.

8 Q. (BY MR. HERMAN:) And the issue is,
9 this study was done on a population, and you don't
10 know if that population is reflective of the Lake
11 and Trumbull County population? Am I understanding
12 you correctly?

13 MR. ARBITBLIT: Object to form.
14 Misstates the record.

15 A. That is not my testimony.

16 Q. (BY MR. HERMAN:) Well, what am I --

17 A. My testimony is that in order to
18 engage in generalizability -- it is not that I
19 don't know. It is that I haven't evaluated the
20 extent to which the treatment utilization
21 population of this particular sample is similar or
22 different than the treatment-using population of
23 Lake and Trumbull County.

24 Q. Okay. And that is in part because
25 you haven't evaluated the treatment-needing

1 population of Lake or Trumbull County, correct?

2 MR. ARBITBLIT: Object to form.

3 A. I have not evaluated the
4 generalizability of this study to that population.

5 Q. (BY MR. HERMAN:) Well, I am asking a
6 slightly different question. I mean, have you
7 evaluated the specific treatment-needing population
8 of Lake and Trumbull County?

9 A. I believe that is included in my
10 report. I have provided a number of estimates
11 about that population.

12 Q. But you don't know the
13 characteristics of that population, for example,
14 whether they are truly drug naïve, correct?

15 MR. ARBITBLIT: Object to form.

16 A. If the population is in treatment,
17 then they certainly are not drug naïve.

18 Q. (BY MR. HERMAN:) Well, drug naïve
19 before they encounter prescription opioids.

20 MR. ARBITBLIT: Object to form. No
21 question pending. There's no question pending.
22 Wait for a question. It is a statement.

23 Q. (BY MR. HERMAN:) Professor Keyes,
24 have you evaluated the characteristics of the
25 population in Lake and Trumbull County that is in

1 need of treatment specifically -- well, I will ask
2 that question first.

3 MR. ARBITBLIT: Object to form.

4 A. Wait. I'm sorry. Is there a
5 question?

6 Q. (BY MR. HERMAN:) Have you evaluated
7 the characteristics of the population in Lake and
8 Trumbull County in need of treatment?

9 A. Yes. I have evaluated some
10 characteristics that are included in my report.

11 Q. Well, all those are estimates,
12 correct?

13 MR. ARBITBLIT: Object to form.

14 A. I mean, statistics are an estimate.

15 Q. (BY MR. HERMAN:) Okay. And you
16 don't know anything about -- for example, let's
17 take your estimate of NAS, potential NAS births.
18 You estimate that there are six NAS births in Lake
19 County, I believe, in Lake County in -- well, one
20 of the years. So I am going to ask you to assume
21 that you provide an estimate of six NAS births in
22 one of the years. Okay. Are you with me?

23 MR. ARBITBLIT: Object to form.

24 A. I am finding the page of the report.
25 I believe you are on Page 51.

1 Q. (BY MR. HERMAN:) I am just asking
2 you to assume that I have your numbers correct,
3 that in one of the years in one of the counties you
4 estimate there were six NAS births. Okay. Are you
5 following what I am asking you to assume?

6 MR. ARBITBLIT: Object to form.

7 A. Yes.

8 Q. (BY MR. HERMAN:) Okay. As to those
9 six mothers who gave birth, do you have any
10 information about what drugs those six mothers
11 used?

12 A. I don't have any information about
13 those six mothers.

14 Q. All right. So you don't know whether
15 the NAS birth, for example, was the result of
16 legitimately prescribed opioids versus illicit
17 opioids?

18 MR. ARBITBLIT: Object to form.

19 A. I do provide estimates of that in
20 various drug-using populations for which there is a
21 broader range of studies that we can use to
22 generalize to inform that question. So the extent
23 to which medical versus nonmedical opioids are used
24 in opioid-using populations, there is a sufficient
25 number of studies that we can provide more

1 generalizable estimates.

2 Q. (BY MR. HERMAN:) Okay. But as to
3 those estimated six mothers, you don't actually --
4 it is an estimate. You don't know anything about
5 those individuals, their drug use trajectory,
6 whether they used a prescribed or illicit opioid,
7 correct?

8 MR. ARBITBLIT: Object to form.
9 Vague. Compound.

10 A. For the six individual -- well,
11 there's not -- the babies are what is reported in
12 the table.

13 Q. (BY MR. HERMAN:) Sure. But it would
14 be the mother's drug use that would result in an
15 NAS birth, correct?

16 A. Right. I have not evaluated the
17 particular drug use history of any mother in Lake
18 and Trumbull County.

19 Q. Do you know how many pharmacies
20 existed in Lake or Trumbull County that dispensed
21 prescription opioids?

22 A. No.

23 Q. So do you have any way of knowing
24 whether any of the estimated births in Lake or
25 Trumbull County in your chart were caused by

1 prescription opioids dispensed by a pharmacy that
2 is a defendant in this litigation?

3 MR. ARBITBLIT: Object to form.

4 A. I can provide expertise on the
5 estimated use of prescription opioids among
6 pregnant women in that area.

7 Q. (BY MR. HERMAN:) Okay. Is the
8 answer to my question no, you have no way of
9 knowing whether any of the estimated NAS births in
10 Lake and Trumbull County were caused by
11 prescription opioids dispensed by a defendant in
12 this case?

13 MR. ARBITBLIT: Object to form.

14 A. That is not my testimony. I think
15 what is in the report provides information that can
16 be used to infer causation with regard to
17 prescription opioid use that would be dispensed by
18 a pharmacy.

19 Q. (BY MR. HERMAN:) But you don't know
20 if it was dispensed -- how would you figure out if
21 one of those births, one of your estimated births
22 was caused by a prescription opioid dispensed by
23 CVS?

24 MR. ARBITBLIT: Object to form.

25 A. One could estimate that, given the

1 distribution of CVS pharmacies in the area.

2 Q. (BY MR. HERMAN:) But to actually
3 know whether a birth was caused -- an NAS birth was
4 caused by a prescription opioid dispensed by CVS,
5 one of six births, you would have to actually show,
6 wouldn't you, that that mother came in contact with
7 an opioid dispensed by CVS, correct?

8 MR. ARBITBLIT: Object to form.
9 Calls for a legal conclusion.

10 A. I would perform epidemiology using
11 the methods that I outlined in the beginning of my
12 report to estimate causation.

13 Q. (BY MR. HERMAN:) Can you -- can you
14 point to -- well, can you explain to me how you
15 would go about figuring out if one of those six NAS
16 births was caused by a particular pharmacy in Lake
17 or Trumbull County?

18 A. So I would do a risk factor analysis,
19 as I have outlined in the beginning of the report,
20 which is how we analyze data in epidemiology. So
21 you would estimate associations using regressions,
22 controlling for confounding factors. You know, in
23 recent years, the number of NAS births in Lake and
24 Trumbull County is quadruple the six that you cite
25 in 2008. So you certainly would have more

1 statistical power if you used more recent years.

2 Q. Okay. And is it likely that a
3 prescription opioid dispensed in 2010 led to an NAS
4 birth in 2018?

5 A. Yes.

6 Q. How would you go about figuring out
7 if a prescription opioid dispensed in 2010 led to
8 an NAS birth in 2018?

9 A. We know very well that the dose and
10 duration of prescription opioid use is associated
11 with the development of opioid use disorder and
12 prolonged opioid use disorder. And so you would
13 examine the onset and duration of prescription
14 opioid use.

15 Q. By that specific individual?

16 MR. ARBITBLIT: Object to form.

17 A. I guess I am not understanding the
18 question.

19 Q. (BY MR. HERMAN:) Well, you would
20 need to know something about the dosage taken by
21 the individual, correct?

22 A. The hypothetical here is about a
23 hypothetical what, single person? I would do a
24 risk factor analysis of, you know, a population,
25 which is what we do in epidemiology.

1 Q. Well, you are estimating that six
2 people had an NAS birth. And so I am saying okay,
3 I want to know whether a prescription opioid
4 dispensed in years before that led to that birth.
5 And you said well, you would need to know something
6 about the dose and duration.

7 And so I am asking you, you would
8 need to know about that specific individual's drug
9 use trajectory, correct?

10 MR. ARBITBLIT: Objection. Vague.
11 Compound. Misstates the record.

12 A. There are a wide variety of sources
13 that one could use to provide a causal analysis,
14 including individual history as well as group
15 history that could be inferred to the individual.

16 Q. (BY MR. HERMAN:) Can drugs other
17 than prescription opioids cause NAS?

18 A. Can drugs other than prescription
19 opioids?

20 Q. Yes.

21 A. Yes.

22 Q. Can drugs other than opioids
23 generally cause NAS?

24 A. NAS is certainly the predominant --
25 opioids are certainly the predominant cause of NAS

1 birth outcomes. And there's some discussion about
2 whether symptoms that occur in neonates that are
3 caused by other drugs are the same syndrome as NAS.
4 So it is a little bit more of a complicated
5 question than a yes or no, but it is possible, I
6 guess I would say.

7 Q. Okay. Can an NAS birth be caused by
8 use of an illegal opioid, like heroin?

9 A. Yes.

10 Q. Fentanyl?

11 A. Yes.

12 Q. Would the use of heroin make it more
13 likely that someone would have an NAS birth?

14 MR. ARBITBLIT: Objection. Vague.

15 A. More likely than what?

16 Q. (BY MR. HERMAN:) Well, more likely
17 than the use of acute dosage of a prescription
18 opioid.

19 MR. ARBITBLIT: Objection. Vague.
20 Incomplete hypothetical.

21 A. It would -- it would depend on the
22 dose and duration of use. So it is a dose response
23 relationship for both.

24 Q. (BY MR. HERMAN:) Okay. All things
25 being equal in terms of dosage, would someone who

1 used heroin be more likely to have an NAS birth or
2 someone who used a prescription opioid?

3 MR. ARBITBLIT: Objection, vague.
4 Incomplete hypothetical.

5 A. If the same amount of opioid is
6 consumed, I would say that they are approximately
7 equal.

8 Q. (BY MR. HERMAN:) Okay. And would
9 your answer be the same for illicit fentanyl?

10 A. The potency of fentanyl is much
11 higher than that of heroin. So in a hypothetical
12 world where the potencies were the same, then the
13 risk would be similar.

14 Q. But so because the potency of
15 fentanyl is higher, if someone was using illicit
16 fentanyl, would they be more likely to have an NAS
17 birth?

18 MR. ARBITBLIT: Object to form.
19 Incomplete hypothetical.

20 A. It depends on the potency of what you
21 are comparing it to.

22 Q. (BY MR. HERMAN:) Can an NAS birth
23 occur as a result of an individual taking
24 prescribed opioid medications?

25 A. Yes.

1 Q. Can an NAS birth occur as a result of
2 an individual taking medically-assisted treatment
3 medications?

4 A. Yes.

5 MR. HERMAN: What exhibit are we on?

6 Q. (BY MR. HERMAN:) Can I ask you,
7 Professor Keyes, while we are figuring out the
8 exhibit number, to take out what is CVS 7-23. And
9 this is going to be Exhibit 14.

10 (Exhibit 14 was marked for
11 identification.)

12 Q. (BY MR. HERMAN:) Do you have it,
13 Professor Keyes?

14 A. I do.

15 Q. Okay. This is an article entitled
16 "Associations of Nonmedical Pain Reliever Use and
17 Initiation of Heroin Use in the United States."
18 And it is authored by Pradip Muhuri; is that
19 correct?

20 A. Uh-huh, yes.

21 Q. Okay. And this is -- this study by
22 Muhuri -- am I pronouncing that right?

23 A. I believe so.

24 Q. This study by Muhuri is one you rely
25 on in your report?

1 A. It is.

2 MR. ARBITBLIT: Counsel, I don't mean
3 to interrupt, but can we have a representation that
4 whatever you are going to ask about Muhuri has not
5 been covered in previous depositions? This article
6 has appeared so many times in so many depositions
7 that it is hard to imagine there's anything new to
8 say about it.

9 MR. HERMAN: Well, I think I am going
10 to ask some new questions, but I may touch on some
11 things that were done before. But I will try to
12 keep that to a minimum.

13 Q. (BY MR. HERMAN:) I'm not sure I got
14 an answer to my question. It is a high-quality
15 research study?

16 MR. ARBITBLIT: Object to form.

17 A. I believe it is a reliable study.

18 Q. (BY MR. HERMAN:) And the lead
19 authors are at SAMHSA?

20 A. The affiliation of the authors is not
21 on the title page, so I actually don't know.

22 Q. Well, up at the top do you see where
23 it says at least the study was put out by SAMHSA?
24 You would agree with that?

25 A. Yes.

1 Q. And that is a substance abuse and
2 mental health administration?

3 A. Yes.

4 Q. That is a leading federal agency for
5 research on substance abuse?

6 MR. ARBITBLIT: Objection.

7 A. I don't -- I don't have any
8 information to know whether it is the leading
9 federal agency. NIDA is also a fairly prominent
10 federal agency so --

11 Q. (BY MR. HERMAN:) Can we agree that
12 it is one of the leading federal agencies for
13 research on substance abuse?

14 A. I think I would be comfortable
15 testifying that it is a federal agency for research
16 on substance abuse.

17 Q. Okay. And they are relying on data
18 from the National Survey on Drug Use and Health?

19 A. Yes.

20 Q. And that is data that is collected by
21 the federal government?

22 A. Yes.

23 MR. ARBITBLIT: I'm going to object
24 that none of this seems new to me, Counsel. It is
25 all repetitive.

1 MR. HERMAN: Well, I am just laying a
2 little background. I think I would ask for a
3 little time.

4
5 Q. (BY MR. HERMAN:) All right. And if
6 you look at Page 3 under "Data and Methods," they
7 have been collecting data since 1971. Do you see
8 that?

9 A. Yes.

10 Q. And for this study, the total sample
11 size, if you look a couple of sentences in, was six
12 hundred and nine thousand -- six hundred and nine
13 thousand people considered at risk for heroin
14 initiation; is that correct?

15 A. Yes.

16 Q. Then it says in the parenthetical
17 "representing an annual average of approximately a
18 hundred and fifty-five million individuals."

19 A. Yes.

20 Q. And that is a large sample, you would
21 agree?

22 A. Yes, it is a large sample.

23 Q. In epidemiology, large samples
24 generally give you better data?

25 MR. ARBITBLIT: Object to form,

1 vague.

2 A. I would not make that conclusion
3 across the board.

4 Q. (BY MR. HERMAN:) Well, other things
5 being equal, a larger sample gives you better data
6 than a smaller one, correct?

7 MR. ARBITBLIT: Object to form,
8 vague.

9 A. A larger sample provides more
10 statistical precision, but the data are not
11 necessarily better.

12 Q. (BY MR. HERMAN:) And then it says
13 there was a total sample size of five hundred and
14 twenty-four thousand people at risk for initiating
15 NMPR use. Do you see that?

16 A. I do.

17 Q. And NMPR stands for nonmedical pain
18 reliever, correct?

19 A. Correct.

20 Q. And in the parenthetical there, it
21 says that represented an annual average of
22 approximately a hundred thirty-two million persons?

23 A. Yes.

24 Q. And that is also a large sample?

25 MR. ARBITBLIT: Object to form.

1 A. That is a large sample.

2 Q. (BY MR. HERMAN:) And this study
3 found that 79.5 percent of people that started
4 using heroin had prior nonmedical pain reliever
5 use, correct?

6 A. Is that Table 5?

7 Q. Well, if you look at, for example,
8 the abstract and if you look a couple sentences up
9 from the bottom, it says four out of five recent
10 heroin initiates, 79.5 percent previously used
11 NMPR.

12 A. So your question was?

13 Q. The study found that 79.5 percent of
14 people who started using heroin had prior
15 nonmedical prescription opioid use?

16 A. So those were recent heroin
17 initiates. So it is not all, all individuals who
18 use heroin. But among recent heroin initiates,
19 79.5 previously used pain relievers nonmedically.

20 Q. Okay. And NMPR means using opioids
21 that weren't prescribed to you or only for
22 experience or feeling you got from using the drug
23 in this study? Do you recall that?

24 MR. ARBITBLIT: Object to form.

25 A. Yes.

1 Q. (BY MR. HERMAN:) And if I could
2 direct you to Table 3.

3 A. Table 3, yes.

4 Q. And that has got four -- well,
5 Table 3 shows data in that Muhuri reported about
6 people in the study who started using heroin,
7 correct?

8 A. Yes.

9 Q. And there are four columns. In the
10 fourth column at right shows data for the full time
11 period the authors looked at, 2002 to 2011?

12 A. Yes.

13 Q. And if you go down to the bottom, you
14 see that 79.5 percent of the people who started
15 heroin had prior NMPR use. Do you see that?

16 A. I see that.

17 Q. And right above that you see that
18 20.5 percent of people who started using heroin had
19 no prior NMPR use?

20 A. I see that.

21 Q. In the same box, you see that 1.1
22 percent of people who started using heroin not only
23 had no prior NMPR use, they had no prior illicit
24 drug use?

25 A. Yes.

1 Q. And right below that you see that
2 19.4 percent of the people who started using heroin
3 did not have prior NMPR use before they started
4 using heroin but they did have prior use of other
5 illicit drugs?

6 A. Yes.

7 Q. And going down to the next box, that
8 is the box for people who had NMPR use before they
9 started heroin, right?

10 A. Can you say that question again?

11 Q. Going down to the next box, we see
12 the people who had NMPR use before they started
13 heroin.

14 A. Yes.

15 Q. And you see that zero percent of the
16 people who started using heroin had only prior NMPR
17 use but no other illicit drugs?

18 A. Yes.

19 Q. And 79.5 percent of people who
20 started using heroin had both prior NMPR use and
21 prior use of other illicit drugs?

22 A. That is what the table says, yes.

23 Q. Everyone in the study who used heroin
24 after misusing prescription opioids also had a
25 history of using other illicit drugs, correct?

1 A. That is correct.

2 Q. And if we look at the people who
3 started using heroin and want to know how many had
4 prior use of illicit drugs other than prescription
5 opioids, we could add up the two numbers Muhuri
6 gives, 19.4 percent and 79.5 percent, correct?

7 MR. ARBITBLIT: Object to form.

8 A. This is -- just to qualify, these are
9 recent heroin initiators and prior use of the
10 illicit drugs that were assessed in the survey.
11 But with those two qualifications, yes, you would
12 add up those two percentages.

13 Q. (BY MR. HERMAN:) Okay. Those are
14 the statistics, though, for the data they looked at
15 for 2002 to 2011, correct?

16 A. Yes.

17 Q. And. So Muhuri's data shows that of
18 people that started using heroin, 98.9 percent have
19 prior illicit drug use other than prescription
20 opioids.

21 MR. ARBITBLIT: Object to form.

22 A. In these data for these individuals
23 with recent heroin initiation, 98.9 percent had a
24 prior illicit drug use as well.

25 Q. (BY MR. HERMAN:) And can I ask you

1 to turn to Figure 6? It is on Page 11.

2 A. Yes.

3 Q. Okay. This figure breaks up people
4 who started using heroin into three groups,
5 correct?

6 A. Yes.

7 Q. The first bar is for a group who
8 started using heroin after misusing prescription
9 opioids, and they also showed dependence or abuse
10 of prescription opioids in the year before they
11 started using heroin, correct?

12 A. Correct.

13 Q. And dependence and abuse is based on
14 definitions in DSM4?

15 A. That is right.

16 Q. Okay. And that is a standard
17 reference work for diagnosing substance abuse
18 conditions?

19 MR. ARBITBLIT: Objection. Time.
20 Vague.

21 Q. (BY MR. HERMAN:) I think you nodded,
22 Professor Keyes, but I think we need a verbal --

23 A. The DSM4 is commonly used in research
24 for diagnosis.

25 Q. For diagnosing substance abuse

1 conditions?

2 A. Yes.

3 Q. And this data shows that people who
4 started heroin, 31.3 percent of them had misused
5 prescription opioids and in the year before
6 starting heroin were abusing or dependent on
7 prescription opioids under the DSM4 definition,
8 correct?

9 A. Among -- yes, among those who started
10 heroin, 31.3 percent had prior use in the past year
11 abuse/dependence of pain relievers.

12 Q. Okay. And the second bar is people
13 who started using heroin after misusing
14 prescription opioids but in the year before
15 starting heroin weren't showing dependence or abuse
16 of prescription opioids, correct?

17 A. Yes.

18 Q. And this shows that 48.2 percent of
19 people who started heroin had misused prescription
20 opioids but in the year before starting heroin
21 weren't abusing or dependent on prescription
22 opioids under the DSM4 definition, correct?

23 A. Yes.

24 Q. And the third bar shows that 21.5
25 percent of people who started heroin had no prior

1 misuse of prescription opioids, right?

2 A. Yes.

3 Q. Okay. In your report, you recognize
4 the people who transition from misuse of
5 prescription opioids to heroin is relatively small,
6 correct?

7 MR. ARBITBLIT: Object to form.

8 A. The transition probability is small.
9 Not the number of people. The number of people is
10 quite large.

11 Q. (BY MR. HERMAN:) Okay. But the
12 percentage of people who transition from
13 prescription opioids to heroin is relatively small,
14 right?

15 MR. ARBITBLIT: Object to form.
16 Vague.

17 A. Among people who use prescription
18 opioids, either prescribed or nonmedically, the
19 proportion that transition to heroin is relatively
20 small. But it translates to a large number because
21 of the commonality of the exposure.

22 Q. (BY MR. HERMAN:) Okay. Muhuri found
23 that in five years after people started misusing
24 prescription opioids, 3.6 percent of them started
25 using heroin, correct?

1 A. Yes.

2 Q. And so after five years, 96.4 percent
3 of people misusing prescription opioids had not
4 tried heroin?

5 A. In this sample, yes.

6 Q. And those figures are for people who
7 use prescription opioids nonmedically, correct?

8 A. Not exactly. The national household
9 survey in these years did not ask about medical
10 use. So there's a large overlap between medical
11 and nonmedical users of prescription opioids. And
12 so a large portion of these nonmedical users had
13 also likely used medically or from a doctor's
14 prescription --

15 Q. Okay. But the 3.6 is of nonmedical
16 prescription, non-medical pain reliever initiates,
17 correct?

18 MR. ARBITBLIT: Object to form.
19 Vague. Misstates.

20 Q. (BY MR. HERMAN:) Well, I will direct
21 your attention to the abstract. And do you have
22 that in front of you?

23 A. I do.

24 Q. Only 3.6 percent of NMPR initiates
25 had initiated heroin use within the five-year

1 period following first nonmedical prescription,
2 nonmedical pain reliever use. Right?

3 A. Yes. That is what the abstract
4 states. I just want to make clear for the record
5 that they didn't -- it is not nonmedical use only.
6 It is this population of people, there's a large
7 overlap with medical use as well, which was not
8 assessed in the survey.

9 Q. Do you know what percentage of people
10 prescribed opioids use nonmedically?

11 A. I believe there's a citation to that.
12 I can pull it up. Most people who use nonmedically
13 have also used medically. And in the reverse --

14 Q. Okay.

15 A. -- the -- I have a citation of that.
16 I will pull it up. I don't think I have the exact
17 figure, but if you would like to pull up the paper,
18 I am sure we can pull up the paper that would give
19 you that information.

20 Q. Well, why don't you just tell me what
21 paper you think provides that information.

22 A. McCabe, "Medical Use and Misuse of
23 Prescription Opioids in U.S. 12th Grade Youth"
24 would provide some of that information. And then
25 also by McCabe, "Trends in Medical and Nonmedical

1 Use of Prescription Opioids Among U.S. Adolescents:
2 1976 to 2015."

3 Q. Okay. Let's maybe keep this simple.
4 You would agree with me that the number of people
5 who use prescription opioids medically is larger
6 than the number of people who use prescription
7 opioids nonmedically, correct?

8 A. Yes.

9 MR. HERMAN: We have been going about
10 an hour. Do people want to take another quick
11 break?

12 THE VIDEOGRAPHER: Stand by.

13 THE REPORTER: Yes.

14 THE VIDEOGRAPHER: We are now off the
15 record. The time on the video monitor is 2:52.

16 (Whereupon, a break was had from 2:52
17 p.m. until 3:02 p.m. EDT)

18 THE VIDEOGRAPHER: We are now on the
19 record. The time on the video monitor is 3:02.

20 Q. (BY MR. HERMAN:) Dr. Keyes, can I
21 ask you to open up what is CVS 7-22.

22 MR. ARBITBLIT: What exhibit is this
23 again?

24 MR. HERMAN: This is going to be
25 Exhibit 15.

1 (Exhibit 15 was marked for
2 identification.)

3 THE REPORTER: Hey, Steve, when you
4 are saying 722, is it 7-22 or, all together, 722?

5 MR. HERMAN: 7-22.

6 Q. (BY MR. HERMAN:) Dr. Keyes, do you
7 have that?

8 A. I do.

9 Q. And is Exhibit 15 an article entitled
10 "Initiation Into Prescription Opioid Misuse Among
11 Young Injection Drug Users"; is that correct?

12 A. It is.

13 Q. And this is an article that you cite
14 in your report at Reference 176?

15 A. Yes.

16 Q. Can I ask you to turn to Page 4 of
17 the section Initiation Into Prescription Opioid
18 Misuse.

19 A. Yes.

20 Q. Okay. And do you see where it says,
21 "Initiation of opioid misuse typically followed
22 first use of alcohol, marijuana and prescription
23 stimulants and preceded initiation of harder drugs,
24 such as cocaine, methamphetamine and heroin?"

25 A. I see that, yes.

1 Q. And did I read that correctly?

2 A. You did.

3 Q. And if you go to the first page,
4 Methods, for this study, they recruited fifty
5 individuals ages sixteen to twenty-five who were
6 injection drug users who had misused prescription
7 opioids at least three times in the past three
8 months, correct?

9 A. Yes.

10 Q. And so those characteristics mean
11 that a hundred percent will misuse prescription
12 opioids?

13 MR. ARBITBLIT: Object to form.

14 A. There were three eligibility
15 criteria: Eighteen to twenty-five years old,
16 misused a prescription drug -- it doesn't say
17 opioids in particular -- and injected a drug within
18 the past three months.

19 Q. (BY MR. HERMAN:) Okay. So a hundred
20 percent will have misused a prescription drug?

21 A. Yes. It says opioids, tranquilizers
22 or stimulants.

23 Q. And a hundred percent will be
24 injection drug users?

25 A. Yes.

1 Q. And can I ask you to go to Table 2?
2 Well, actually, let me ask you this first: On Page
3 4, right back where we were before, do you see
4 where it says, "over four-fifths (N=43) initiated
5 opioid misuse prior to heroin, which occurred two
6 years earlier on average"?

7 A. I do.

8 Q. Okay. And what that is saying is
9 that eighty-six percent had misused prescription
10 opioids before they used heroin, just sequentially,
11 correct?

12 MR. ARBITBLIT: Object to the form.

13 A. That's right.

14 Q. (BY MR. HERMAN:) And on average,
15 that misuse occurred two years earlier than the
16 person -- before when the person began using
17 heroin?

18 A. Yes.

19 Q. If you go to Table 2, Table 2 lists a
20 number of substances, and it has got three columns,
21 and the last column shows the total percentage of
22 the population in the study that had used the
23 substance listed, correct?

24 A. Yes.

25 Q. So for the first one, it shows that a

1 hundred percent of the population in the study had
2 misused marijuana, right?

3 A. That is right.

4 Q. And a hundred percent had misused
5 alcohol?

6 A. Yes. Used alcohol.

7 Q. And eighty-two percent had used
8 stimulants?

9 A. Yes.

10 Q. Okay. And then a hundred percent had
11 used opioids, presumably prescription opioids and
12 heroin, correct?

13 A. That's right.

14 Q. And then ninety-eight percent had
15 used cocaine?

16 A. Yes.

17 Q. Ninety-four percent had used
18 mushrooms?

19 A. Yes.

20 Q. Ninety-two percent had used
21 tranquilizers?

22 A. Yes.

23 Q. Ninety-six percent had used ecstasy?

24 A. Yes.

25 Q. Eighty-six percent had used crack?

1 A. Yes.

2 Q. Okay. You can set that aside. And
3 can I ask you to open up 7-21. This will be
4 Exhibit 16.

5 Do you have it, Professor Keyes?
6 (Exhibit 16 was marked for
7 identification.)

8 A. I do.

9 Q. (BY MR. HERMAN:) So Exhibit 16 is an
10 article titled "Injection and Sexual Activity [sic]
11 HIV/HCV Risk Behaviors Associated With Non-Medical
12 Use of Prescription Opioids Among Young Adults in
13 New York City"; is that correct?

14 A. That's correct.

15 Q. And this is another article you cite
16 in your report?

17 A. I do. Do you know the citation
18 number?

19 Q. It is 164.

20 A. Yeah.

21 Q. And if you go to Page 3 and look at
22 the Methods section, this was a study that involved
23 forty-six New York City young adults ages eighteen
24 to thirty-two who engaged in non-medical
25 prescription opioid use who were recruited for

1 individual interviews. "Twenty-three participants
2 were referred by service providers (drug treatment
3 programs, an outreach programs for young injectors,
4 key informants, other research projects). And the
5 remaining twenty-three were recruited via chain
6 referral from other participants." Is that right?

7 A. That's right.

8 Q. And if you look at Page 15 and the
9 last paragraph, do you see the sentence -- it is
10 the second sentence that begins "Because this is a
11 qualitative study based on interviews conducted
12 with a relatively small number of participants who
13 were sampled via non-probabilistic methods, the
14 results are not intended to be generalizable to all
15 young adult non-medical PO users." Do you see
16 that?

17 A. I do.

18 Q. And that is some of what I think you
19 were talking about earlier that you have to look at
20 the population and what was being looked at to know
21 whether the results would generalize to a larger
22 population, correct?

23 MR. ARBITBLIT: Object to form.

24 A. There were a number of considerations
25 with respect to generalizability. And population

1 comparability is one part of what we would
2 evaluate. The other part would be the strength and
3 variety of the evidence that is being offered to
4 generalize.

5 Q. (BY MR. HERMAN:) Okay. And then if
6 you go a little further down, they say, "We used
7 quantitative data to precisely characterize our
8 data, not to make statistical inferences about a
9 larger population." Do you see that?

10 A. I do.

11 Q. And do you see on the next page, the
12 study says, "Similarly, since the majority of study
13 participants engaged in regular daily or nearly
14 daily PO use, the behaviors and experiences of more
15 casual, sporadic PO misusers may be
16 underrepresented"?

17 A. I see that.

18 Q. And I read that correctly?

19 A. Yes.

20 Q. Can I ask you to turn to Page 5? And
21 after the first block quote, do you see where it
22 says, "Early PO use [sic]" -- and PO means
23 prescription opioid, correct?

24 A. Prescription opioid.

25 Q. "Early PO misuse was typically

1 described as taking place within a normative peer
2 context in which poly-drug and poly-pharmaceutical
3 use was widely accepted. Some participants spoke
4 of attending pill parties." Do you read that?

5 A. Yes. The rest of the sentence says,
6 "where prescription opioids were used concurrently
7 with benzodiazapines, prescription stimulants and
8 marijuana."

9 Q. What is your understanding of
10 normative peer context?

11 MR. ARBITBLIT: Object to form.

12 A. In terms of how the authors are using
13 it in this sentence? Or a broader --

14 Q. (BY MR. HERMAN:) Sure. How they are
15 using it in this sentence.

16 A. I would -- I would point to how the
17 youth uses it in their quotation. That it was a
18 gathering of four to fifteen people.

19 Q. Okay. And the context was one in
20 which, among this population, poly-drug use and
21 poly-pharmaceutical use was widely accepted,
22 correct?

23 A. In this sample, the authors report
24 that poly-drug and poly-pharmaceutical use was
25 widely accepted.

1 Q. And if you look at the block quote
2 above that, it is describing, from one of these
3 interviews, someone said, "I first used opiate
4 painkillers when I was seventeen. It was very
5 simple. Basically somebody (stepfather) in my
6 household had a massive back surgery. He didn't
7 really like the way they made them feel, so they
8 were just sitting, you know, sort of around the
9 house. He would get them filled and never take
10 them and never seemed to notice they were missing."
11 Did I read that correctly?

12 A. Yes.

13 Q. And do you believe that it is
14 appropriate for a doctor to prescribe prescription
15 opioids for a massive back surgery?

16 MR. ARBITBLIT: Object to form.

17 A. It would depend on the context.

18 Q. (BY MR. HERMAN:) Okay. And -- well,
19 in this scenario, what this person is describing,
20 right, is that the stepfather got a prescription
21 from a doctor for massive back surgery, correct?

22 A. Presumably, I am inferring -- I mean
23 I only have the same information that is available
24 to me, and it says that the stepfather had a
25 massive back surgery. It doesn't say where he got

1 the opioid painkillers from, so I wouldn't --

2 Q. You can't infer that from "he would
3 get it filled" --

4 A. Right. The information on the page
5 does not describe where it is from.

6 Q. Okay. But do you think it is a fair
7 inference that he was getting the prescription
8 filled that was prescribed by a doctor for a
9 massive back surgery?

10 MR. ARBITBLIT: Object to form.

11 A. I think that -- that could be a fair
12 assumption. I just don't have any more information
13 than you with regard to what is on this page.

14 Q. (BY MR. HERMAN:) Well, I am going to
15 ask you to assume that his doctor prescribed the
16 prescription opioids for his massive back surgery,
17 intending that they would be used for a legitimate
18 medical purpose of relieving his pain.

19 Okay. Do you understand what I am
20 asking you to assume?

21 A. There are a lot of assumptions
22 embedded in that question.

23 Q. Well -- I am asking -- I am asking
24 you to assume. So, yes, there is an assumption
25 that this person had a massive back surgery, and

1 his doctor prescribed him opioids, intending that
2 they would be used for the legitimate medical
3 purpose of relieving post-operative pain. Okay.
4 You understand what I am asking you to assume?

5 MR. ARBITBLIT: Object to form.
6 Incomplete hypothetical.

7 A. I generally understand the scenario.
8 It is just -- it is not clear what opioids, how
9 much -- I mean clearly there was such a surplus
10 supply left over that -- I mean within the confines
11 of this example.

12 Q. (BY MR. HERMAN:) That can happen,
13 right? You have a number of studies that you cite
14 in your report where doctors are prescribing things
15 for things like C-sections, mastectomies, thoracic
16 surgery, where the study is looking at how their
17 prescription opioid pills are left over after
18 surgery, correct?

19 MR. ARBITBLIT: Object to form.

20 A. There are studies that describe
21 unused medication after -- that people received,
22 that people don't use of their opioid medication.

23 Q. (BY MR. HERMAN:) Yeah, including --
24 you cite one that estimates there would be a
25 hundred million prescription opioid pills left over

1 after dental surgeries per year, correct?

2 A. Which study is that?

3 Q. Well, do you not recall that study?

4 MR. ARBITBLIT: Object to form.

5 A. I just would -- I would prefer to see
6 the study before testifying what it says.

7 Q. (BY MR. HERMAN:) Okay. We can come
8 back to that. But going to my hypothetical here
9 with -- assuming that the doctor wrote that
10 prescription intending that it would be used by the
11 patient to relieve pain for post-operative --
12 post-operative pain for a massive back surgery, do
13 you think there would be anything wrong with a
14 pharmacy filling that prescription?

15 MR. ARBITBLIT: Object to form.
16 Incomplete hypothetical. Asked and answered.

17 A. My general understanding is that
18 pharmacies have responsibilities in terms of
19 dispensing medication that has been prescribed.
20 And there's no information in this hypothetical
21 scenario to know whether the pharmacy that
22 dispensed this prescription that was then used by a
23 twenty-five year old was dispensed responsibly.

24 Q. (BY MR. HERMAN:) Well, I am asking
25 you to assume that it was dispensed pursuant to a

1 prescription for postoperative pain following a
2 massive back surgery. Do you take issue with the
3 pharmacy filling such a prescription written by an
4 FDA -- by a licensed prescriber for an FDA-approved
5 medication?

6 MR. ARBITBLIT: Object to form.
7 Asked and answered. Incomplete hypothetical.

8 A. I have no information on whether the
9 pharmacy fulfilled their responsibilities with
10 regard to this particular prescription.

11 Q. (BY MR. HERMAN:) Okay. Let's
12 assume -- let's assume that the prescription was
13 written for a legitimate medical purpose for
14 post-operative pain following a massive back
15 surgery. Okay. I am asking you to assume that
16 now.

17 MR. ARBITBLIT: There's no question
18 pending.

19 Q. (BY MR. HERMAN:) And the pharmacy
20 appropriately filled that prescription as a
21 prescription written by a licensed medical provider
22 for an FDA-approved medication for a legitimate --
23 prescribed for a legitimate medical purpose. So I
24 am asking you to assume that the prescription was
25 written appropriately and filled appropriately,

1 okay?

2 A. There's no information on whether
3 there was a co-prescription with benzodiazepines.
4 There's no information whether there were multiple
5 prescriptions written and this person was getting
6 it from multiple pharmacies, which also should be a
7 responsibility of the pharmacist to check. So I
8 can't answer that hypothetical without information
9 on what other potential --

10 Q. I understand you don't want to answer
11 the hypothetical that I am asking. But I'm asking
12 a very specific hypothetical. It is a prescription
13 written by a doctor for a legitimate medical
14 purpose. You agree with me that a pharmacy can
15 legally fill a prescription written by a licensed
16 prescriber for an FDA-approved medication for a
17 legitimate medical purpose, correct?

18 MR. ARBITBLIT: Object to form.
19 Argumentative, badgering, incomplete hypothetical.

20 A. Is there a co-prescription with
21 benzodiazepines in your hypothetical scenario?

22 Q. (BY MR. HERMAN:) Professor Keyes,
23 I'm not trying to fight with you here. I am
24 limiting it to a prescription opioid written for a
25 legitimate medical purpose, appropriately filled by

1 the pharmacy. That is the hypothetical. Do you
2 understand?

3 MR. ARBITBLIT: Object to form.

4 A. I understand the hypothetical, and it
5 cannot be answered yes or no without additional
6 information.

7 Q. (BY MR. HERMAN:) I haven't even
8 asked my question. I am just asking you to assume
9 appropriately written, appropriately filled. Got
10 it?

11 MR. ARBITBLIT: Object to form.

12 Q. (BY MR. HERMAN:) Okay.

13 MR. ARBITBLIT: Assumes facts not in
14 evidence. Incomplete hypothetical.

15 Q. (BY MR. HERMAN:) Now, what this
16 person describes here is that the patient who
17 received an appropriate medication did not properly
18 store or dispose of the medication, correct?

19 MR. ARBITBLIT: Object to form.
20 Assumes facts not in evidence. Incomplete
21 hypothetical. Misstates the record.

22 Q. (BY MR. HERMAN:) Well, this
23 description says the stepfather didn't really like
24 the way they made him feel so they were just
25 sitting, you know, sort of around the house. Do

1 you think that describes a scenario where
2 prescription opioids were not appropriately
3 disposed of or stored?

4 MR. ARBITBLIT: Objection.
5 Incomplete hypothetical.

6 A. I don't know how they were stored in
7 this hypothetical scenario. I only know what you
8 know, that they were sitting around the house.

9 Q. (BY MR. HERMAN:) And that -- a
10 pharmacy can't control whether a patient
11 appropriately prescribed prescription opioids that
12 are appropriately dispensed are just sitting around
13 a house?

14 MR. ARBITBLIT: Objection.
15 Incomplete hypothetical.

16 A. I would say a pharmacy can control
17 whether the person received the opioid prescription
18 in the first place. Certainly they are a part of
19 that chain of receipt.

20 Q. (BY MR. HERMAN:) Sure. And here I
21 have asked you to assume, following a massive back
22 surgery, that these prescriptions were
23 appropriately prescribed and appropriately filled.
24 Everything is appropriate when they leave the
25 pharmacy. Can the pharmacy control how the patient

1 stores prescription opioids?

2 MR. ARBITBLIT: Objection.

3 Incomplete hypothetical.

4 A. Again, I -- the hypothetical scenario
5 is asking -- has not established that the pharmacy
6 did the appropriate responsibilities to ensure that
7 this medication was being prescribed safely.

8 Q. (BY MR. HERMAN:) You are unwilling
9 to accept what I am asking you to assume, that
10 everything was appropriate with the prescription
11 when it left the pharmacy. You are unwilling to
12 accept what I am asking you to assume?

13 A. I -- I can engage in the -- in the
14 hypothetical. I just --

15 Q. Well, I have been asking you to do
16 that for a while.

17 MR. ARBITBLIT: Counsel, you have
18 asked so many different hypotheticals, and now you
19 are badgering. Some are based on the article and
20 some are not. I will object. It is confusing and
21 argumentative and badgering.

22 Q. (BY MR. HERMAN:) Well, do you agree
23 with me that a pharmacist and a pharmacy cannot
24 control how appropriately dispensed prescriptions
25 are stored?

1 A. I would agree that once a
2 prescription leaves the pharmacy, the pharmacy
3 cannot monitor how it is stored.

4 Q. And can't control how it is disposed
5 of?

6 A. That is right.

7 Q. Can't control whether the patient
8 takes more than the doctor instructed the patient
9 to take at one time?

10 MR. ARBITBLIT: Object to form.

11 A. Again, I do think the pharmacy has
12 some responsibility in terms of ensuring that the
13 prescriptions that are dispensed by the pharmacy
14 are appropriately dispensed.

15 So -- I would not agree with that
16 statement.

17 Q. (BY MR. HERMAN:) Yeah, again, I
18 think -- I understand that you don't -- but I am
19 asking you, prescriptions appropriately dispensed,
20 you agree that after that point, a pharmacy and a
21 pharmacist cannot control whether the patient takes
22 the medication as prescribed?

23 THE REPORTER: Someone needs to mute
24 themselves or I hear something in the background.

25 A. I don't think I would agree with that

1 as a blanket statement, given that the pharmacy has
2 control over the number of pills that are
3 dispensed.

4 Q. (BY MR. HERMAN:) Well, it is a
5 doctor that decides on the amount and dosage in a
6 prescription, correct?

7 MR. ARBITBLIT: Object to form.
8 Misstates the evidence.

9 A. The -- the prescription is written
10 for a specific amount and dosage.

11 Q. (BY MR. HERMAN:) Can I ask you to go
12 to -- can I ask you to go to Page 19 of your
13 report. And on Page 19, towards the bottom, you
14 are discussing one of the studies. And you say,
15 "Most problematically, the article reports on an
16 overall association between any opioid use and
17 opioid use disorder, but this association is
18 uninformative and essentially pointless. It is
19 well documented that risk of opioid use" -- opioid,
20 sorry -- "well documented that risk of
21 opioid-related adverse outcomes are heterogenous by
22 dose and duration of use."

23 Do you see that?

24 A. I do.

25 Q. And I read that correctly?

1 A. Yes.

2 Q. And when you say that risk of
3 opioid -- when you say, "risks of opioid adverse
4 outcomes are heterogenous by dose and duration,"
5 you mean that the risk differs depending on the
6 dose and duration that a patient takes, correct?

7 A. Yes.

8 Q. And then on Page 20, near the top of
9 the page, you say, "This same issue underlines
10 Cepeda, et al., which was also included in the
11 Higgins review; the study includes data for almost
12 forty thousand patients from insurance claims
13 databases and reports an overall association
14 between opioid prescriptions and claims-recorded
15 opioid use disorder, without disaggregating the
16 dose and duration. Such information is
17 uninformative for assessment of opioid use disorder
18 risk with prescription opioid use, given the known
19 heterogeneity," correct? Did I read that
20 correctly?

21 A. Yes.

22 Q. And what I understand you to be
23 saying there, and correct me if I am wrong, is your
24 view is that it is essentially pointless to give an
25 association between opioid use and opioid use

1 disorder that doesn't recognize there will be
2 differences in risk, depending on how one uses
3 prescription opioids, correct?

4 A. That is not exactly what the report
5 says. I think overall assessment of the
6 relationship between opioid use and opioid use
7 disorder do provide some information, but we know
8 there's a dose response relationship between dose
9 and duration and opioid use disorder and overdose.
10 So it is, you know, important to evaluate that in
11 an overall body of literature, to provide that
12 information.

13 Q. Right. You have got to separate --
14 if you were to apply the risk from, for example,
15 all acute users, you couldn't extrapolate that risk
16 to all users, right? It is informative to -- by
17 dose and duration, right? I'm sorry. I asked
18 about four questions in there. But let me strike
19 that and ask a different one.

20 But what you are saying is, when you
21 are evaluating risk, there are different risks,
22 depending on whether someone takes an acute dose or
23 a high dose, correct?

24 MR. ARBITBLIT: Objection, vague.

25 A. It really depends on what the

1 research question is and what you are looking at.
2 There are a number of ways to evaluate risk of
3 opioid use disorder after opioid use. One way to
4 evaluate it that is very informative is to see how
5 different the risk is based on dose and duration.
6 And the risk of opioid use disorder is much higher
7 when you have high dose and high duration.

8 Q. (BY MR. HERMAN:) Yeah, but you
9 couldn't -- it would be uninformative, to borrow
10 your language, to use the risk percentage for acute
11 users and apply that to long-term users, correct?

12 A. It would depend on the specific
13 context in which someone was trying to make those
14 extrapolations. I wouldn't want to make a blanket
15 statement.

16 Q. But so do you -- let's say I took a
17 population of all acute users and presumably came
18 up with a relatively low percentage who developed
19 OUD. It would be wrong for me to take that
20 percentage and apply it to long-term users,
21 correct?

22 MR. ARBITBLIT: Objection to the
23 form.

24 A. I would need more information about
25 the studies that you were trying to extrapolate

1 between.

2 Q. (BY MR. HERMAN:) Okay. Well, let's
3 look at -- can I ask you to take out 7 -- CVS 7-18,
4 which will be Exhibit --

5 MR. HERMAN: What are we up to now?
6 7-18 --

7 MR. ACTON: 7-18? 7-18?

8 MR. HERMAN: Yes.

9 MR. ACTON: 17.

10 MR. HERMAN: This is Exhibit 17,
11 Professor Keyes. Do you have it?

12 (Exhibit 17 was marked for
13 identification.)

14 A. I do.

15 Q. (BY MR. HERMAN:) And this is a study
16 that discusses -- or that is titled "The Role of
17 Opioid Prescriptions in Incident Opioid Abuse and
18 Dependence Among Individuals with Chronic
19 Non-Cancer Pain: The Role of Opioid Prescription";
20 is that correct?

21 A. Yes.

22 Q. And this is an article you cite in
23 your report?

24 A. I do.

25 Q. And if you look at Page 3 under

1 Measures, Independent Variables. So this report
2 looked at days of use. And so acute was defined --
3 or none would be zero. Acute was one to ninety
4 days, or chronic was ninety-one plus days. Is that
5 correct?

6 A. Yes.

7 Q. And then if you look at the next
8 page, it also looked at dosage. And the average
9 daily dose was measured in morphine equivalents and
10 grouped as none (zero milligrams), low dose (one to
11 36 milligrams), medium dose (36 to 120 milligrams),
12 and high dose (120 plus milligrams). Is that
13 correct?

14 A. Yes.

15 Q. Okay. And if you look at Page 5
16 under Results, there were five hundred and
17 sixty-eight thousand six hundred and forty
18 individuals in this analytical sample; is that --
19 is that correct?

20 A. Yes.

21 Q. Okay. And is that a fairly large
22 sample?

23 MR. ARBITBLIT: Object to form.

24 A. That is a large sample, yes.

25 Q. (BY MR. HERMAN:) And the majority of

1 the sample had no prescribed opioid use in the
2 twelve months following the index date, correct?

3 A. 65.3 percent had no opioid use.

4 Q. A --

5 A. No prescribed opioid use.

6 Q. And thirty-five -- the flip side of
7 that is approximately thirty-five percent of the
8 sample received opioids?

9 A. Yes.

10 Q. And low dose acute and medium dose
11 acute were the most common type of the opioid use?

12 A. Yes.

13 Q. 15.9 percent for low dose acute?

14 A. Yes.

15 Q. 14.7 percent for medium dose acute?

16 A. Yes.

17 Q. Okay. And high dose chronic use was
18 the least common, 0.1 percent of the sample?

19 A. Yes.

20 Q. And then among the entire sample
21 prescribed opioids, 94.5 percent were acute users?

22 MR. ARBITBLIT: Objection.

23 A. That is right.

24 Q. (BY MR. HERMAN:) And if you go down
25 to the second paragraph, it says, "Among the total

1 sample, four hundred and ninety-seven (0.1 percent)
2 had a new diagnosis of OUD in the post-index
3 period." Did I read that correctly?

4 A. You read that correctly.

5 Q. And because such a large percentage
6 of the sample is acute users, you wouldn't apply
7 that 0.1 percent to chronic users, correct?

8 MR. ARBITBLIT: Object to form.
9 Misstates the evidence.

10 MR. HERMAN: Well, I am asking.

11 Q. (BY MR. HERMAN:) Could I take that
12 0.1 --

13 MR. ARBITBLIT: Your .1 is to the
14 whole sample. You are asking -- never mind.
15 Sorry. Object to form. Misstates the evidence.

16 Q. (BY MR. HERMAN:) Could you take that
17 0.1 percent of new diagnosis of OUD and apply that
18 to a population that included only chronic users
19 and expect to get the same results?

20 MR. ARBITBLIT: Object to form.
21 Misstates the evidence.

22 A. I don't -- what is the goal of the
23 analysis in the hypothetical?

24 Q. (BY MR. HERMAN:) Well, I think I am
25 trying to follow what you are saying in your

1 report, that something that just looks at a patient
2 population and doesn't account for heterogeneity of
3 dosage and duration wouldn't extrapolate to --
4 would be uninformative.

5 MR. ARBITBLIT: Object to form.
6 Vague.

7 Q. (BY MR. HERMAN:) All right. Let's
8 keep going.

9 A. I mean .1 percent is the total
10 percentage of new OUD diagnosis in the total
11 sample.

12 Q. (BY MR. HERMAN:) Okay. Let's just
13 keep going.

14 Next down it says, "The unadjusted
15 rates of post-index OUD diagnosis for the various
16 opioid dose/days categories were 0.12 percent (111
17 out of 90,415) per low dose acute; 0.72 percent (50
18 out of 6,902) for low dose chronic; 0.12 percent
19 (111 out of 83,542) for medium dose acute; 1.28
20 percent (47 out of 3,654) for medium dose chronic;
21 0.12 percent (15 out of 12,378) for high dose
22 acute; and 6.1 percent (23 out of 378) for high
23 dose chronic."

24 Was that the results of the
25 unadjusted rates of post-index OUD diagnosis for

1 the various opioid dose/days categories that they
2 found?

3 A. Yes.

4 Q. Do you know how many prescription
5 opioid patients in Lake and Trumbull County fit
6 into the category of acute patients?

7 A. No.

8 Q. Do you know how many prescription
9 opioid users in Lake and Trumbull County were low
10 dosage patients?

11 A. I am not aware.

12 Q. Do you know how many patients who
13 fill prescriptions at CVS fit into each of the
14 categories discussed in this report?

15 A. I don't.

16 Q. Would your answer be the same for
17 Rite Aid, Giant Eagle, Walgreens and Walmart?

18 A. Yes.

19 Q. Besides dose and duration, there are
20 other individual risk factors that matter -- that
21 matter in terms of assessing risk to a particular
22 patient, correct?

23 A. You mean risk for development of OUD?

24 Q. Yes. Yes.

25 A. So the question is whether there are

1 risk factors for OUD over and above dose and
2 duration. That is the question?

3 Q. That is the question.

4 A. OUD -- dose and duration are the
5 strongest risk factors for OUD development, but
6 other risk factors include things like, you know,
7 sex and previous history of psychiatric disorders
8 and drug use and other -- kind of individual
9 vulnerabilities.

10 Q. Okay. Sticking with your counsel's
11 admonition, you have discussed different individual
12 level risk factors in your previous testimony at
13 deposition and the testimony you gave in New York,
14 correct?

15 A. I believe so.

16 Q. And you have also discussed
17 individual risk factors in articles that you have
18 authored?

19 A. I have.

20 Q. Is there any reason that individual
21 risk factors discussed in your previous testimony
22 and articles would not apply to people in Lake
23 County and Trumbull County?

24 MR. ARBITBLIT: Object to form.

25 A. The -- I would look at each risk

1 factor specifically, but in general the risk
2 factors that have been identified in the
3 literature, I would -- I would make the assumption
4 that they would generally generalize to Lake and
5 Trumbull County.

6 Q. (BY MR. HERMAN:) Sure. Like if
7 something was a differentiation on urban versus
8 rural and one of the counties wasn't rural or
9 urban, it wouldn't apply. But generally they would
10 apply, correct?

11 A. I would look at each one
12 specifically, so I wouldn't want to make a blanket
13 statement. But, you know, depending on which
14 specific risk factors we are talking about, I could
15 make a determination of generalizability.

16 Q. Okay. But the ones you mentioned,
17 sex, mental health history, previous drug use, no
18 reason to think that those wouldn't be risk factors
19 for individuals in Lake and Trumbull County?

20 A. I don't have reason to think that
21 they wouldn't be.

22 Q. Okay. And can I ask you to look at
23 Page 11 of your report? And the last sentence
24 where you say, "This framework does not preclude or
25 ignore that addiction and related harms are

1 multi-factorial in their etiology." What is
2 "multifactorial in their etiology"?

3 A. I'm not seeing on Page 11 --

4 Q. It is right above "Methodology For
5 Review of the Evidence."

6 A. Okay. So the full sentence is "This
7 framework does not preclude or ignore that
8 addiction and related harms" --

9 THE REPORTER: I'm sorry. Slow down,
10 please.

11 A. I'm sorry. Do you want to read the
12 whole sentence?

13 Q. (BY MR. HERMAN:) Well, I am really
14 just asking you a question in that sentence. But
15 what is "multi-factorial in their etiology"?

16 A. That means that there can be multiple
17 causal risk factors for an outcome.

18 Q. Okay. When you say a disease is
19 multi-factorial, you mean that a single cause does
20 not produce a disease but the combination of many
21 causes produce a disease, correct?

22 MR. ARBITBLIT: Object to form.

23 A. Not necessarily.

24 Q. (BY MR. HERMAN:) That is not how you
25 described multi-factorial in your textbook,

1 Epidemiology Matters?

2 A. It means that there can be multiple
3 causal risk factors that simultaneously produce an
4 outcome. Sometimes that can be multiple risk
5 factors -- multiple causes interacting with each
6 other. Cigarette smoking is a good example.
7 Smoking is a cause of lung cancer, but not all
8 smokers get lung cancer. So there have to be other
9 factors too.

10 Q. Just sticking with dosage and
11 duration abuse for a moment. In your report you
12 cite the Jamison study as having the highest rates
13 of addiction, correct? Do you recall that?

14 MR. ARBITBLIT: Object to form.
15 Misstates.

16 A. I just want to find the -- I believe
17 I am referring to a review article. I say the
18 highest rate of addiction in the review article
19 documented --

20 Q. (BY MR. HERMAN:) Fair enough. In
21 bold, it is the highest in bold -- Jamison has the
22 highest rates of addiction of study discussed in
23 the Vowles article, correct?

24 A. Yes, the study where all patients
25 were on long-term prescribed opioids for noncancer

1 pain.

2 Q. And as you say on Page 16,
3 "Individuals in the study had been using opioids
4 for an average of five to six years. 34.1 percent
5 of the sample had evidence of opioid use disorder,
6 including thirty-one percent of men and 36.7 of
7 women, indicating a high level of opioid use
8 disorder when patients are assessed with validated
9 instruments as well as objective measures of the
10 presence of opioids, such as urine toxicology,"
11 correct? That is the full sentence?

12 A. That is the full sentence.

13 Q. And so after using prescription
14 opioids for an average of five to six years,
15 approximately two-thirds of the patients did not
16 exhibit an opioid use disorder?

17 A. A little less than that, thirty-four
18 percent. So I guess that would be one hundred
19 minus thirty-four percent.

20 Q. So approximately sixty-six percent,
21 making --

22 A. Approximately.

23 Q. 65.9 percent?

24 A. Correct.

25 Q. Okay. So would you agree with me

1 that characteristics of opioid use, like dose and
2 duration, can only tell you someone might be at
3 risk for opioid use disorder?

4 MR. ARBITBLIT: Object to form.

5 A. No. I would not agree with that.

6 Q. (BY MR. HERMAN:) Well, if I told you
7 that someone used opioids for five to six years,
8 would you be able to tell me if that person was in
9 the 65.9 percent who didn't develop a disorder or
10 the 34.1 percent who did develop an opioid use
11 disorder?

12 MR. ARBITBLIT: Object to form.
13 Incomplete hypothetical.

14 A. So in this study, the 34.1 percent of
15 people who had opioid use disorder were not at risk
16 for opioid use disorder. They had opioid use
17 disorder.

18 Q. (BY MR. HERMAN:) I'm asking --

19 A. So --

20 Q. Sorry. I didn't mean to cut you off.
21 Please --

22 A. I don't understand the hypothetical.

23 Q. Well, I am asking you, in this study
24 people who used opioids for five to six years, 34.1
25 percent developed an opioid use disorder, correct?

1 A. Yes.

2 Q. And so what you say with that is
3 duration of use increases your risk for developing
4 an opioid use disorder, right?

5 A. That is not a conclusion that I draw
6 from this study. But from the body of evidence,
7 yes, duration is a risk factor for opioid use
8 disorder.

9 Q. Okay. But if a person -- if I told
10 you a person had used opioids for five to six
11 years, would you only be able to tell me that
12 person had an increased use of developing an opioid
13 use disorder as opposed to being able to tell me
14 whether that person did, in fact, develop an opioid
15 use disorder?

16 MR. ARBITBLIT: Objection, vague.

17 A. If I was given no additional
18 information other than the duration of use, you
19 could say what the probability is that they
20 developed opioid use disorder, but no definitive,
21 much like any risk factor.

22 Q. (BY MR. HERMAN:) And what additional
23 information -- well, let me ask it this way: Well,
24 what additional information would you need to be
25 able to tell me if that person did, in fact,

1 develop an opioid use disorder?

2 A. In epidemiology we quantify things in
3 terms of probabilities and risk factors. And so
4 with additional information we could refine the
5 probability and risk factor assessment.

6 Q. Okay. But to actually know whether
7 the person developed an opioid use disorder, you
8 would have to have a diagnosis code? What would
9 you need?

10 MR. ARBITBLIT: Object to form,
11 vague.

12 A. To know whether a person develops
13 opioid use disorder, one would assess for opioid
14 use disorder.

15 Q. (BY MR. HERMAN:) And you haven't
16 looked at patient files for individuals in Lake or
17 Trumbull County to see if any particular patient
18 has an opioid use disorder diagnosis, correct?

19 A. No.

20 Q. Earlier today, I believe you
21 testified that doctors -- you were troubled with
22 the term "legitimate medical purpose" because you
23 felt doctors did not have the right information
24 about the risks and benefits of opioids at the time
25 they made the prescription, correct?

1 A. I don't -- that is not a complete
2 characterization of my testimony.

3 Q. Okay. Well, why don't we -- if I
4 could ask you to open up Exhibit 4.

5 MR. HERMAN: But what is CVS 4 --
6 what exhibit are we on?

7 (Off-the-record discussion.)

8 Q. (BY MR. HERMAN:) This is going to be
9 Exhibit 18.

10 (Exhibit 18 was marked for
11 identification.)

12 Q. (BY MR. HERMAN:) This is a copy of
13 the transcript of your testimony from your April
14 29th, 2019, deposition in the Cuyahoga and Summit
15 County case?

16 A. Yes.

17 Q. And can I ask you to turn to Page 82?
18 And if you look at Line 16, I asked you, "You would
19 agree that a prescriber is only supposed to write
20 prescriptions for legitimate medical reasons,
21 correct?"

22 And you answered, "I think that
23 prescribers are prescribing based on a set of
24 information that they are given and that oftentimes
25 the risk of opioids were" -- you said overstated

1 but you correct it later to understated, "the risk
2 of prescription opioids were understated." So I
3 think --

4 A. I'm sorry. I don't mean to interrupt
5 you, but I just want to find the page.

6 Q. Oh, I'm sorry. I thought you were
7 there.

8 A. No, I'm sorry. I was looking at the
9 page at the bottom, not the page --

10 Q. Okay. I apologize.

11 A. I apologize.

12 Q. It is Page 22 of the overall.

13 A. I see. Okay. Sorry.

14 Q. So I asked you, "You would agree that
15 a prescriber is only supposed to write
16 prescriptions for legitimate medical reasons,
17 correct?"

18 And you answered, "I think that
19 prescribers are prescribing based on a set of
20 information that they are given, and oftentimes
21 that the risk of opioids were" -- and you corrected
22 it later to understated, "the risk of prescription
23 opioids were understated, and so I think that
24 physicians are in a difficult position when they
25 are trying to write prescriptions for legitimate

1 medical reasons."

2 Is that what I asked you and the
3 answer you gave?

4 A. Yes.

5 Q. Okay. And one of the opinions, if
6 you look at your report on Page 4, Opinion Number
7 4, the first sentence is, "Medical use of opioids
8 is associated with the development of opioid use
9 disorder at higher rates than were reported by drug
10 manufacturers." Did I read that opinion correctly?

11 A. Yes.

12 Q. And is that what you were referring
13 to in your testimony that we just looked at when
14 you said the risks were understated?

15 MR. ARBITBLIT: Object to form.

16 A. Opioid use disorder is one of many
17 risks of using an opioid. So I said the risks were
18 understated, and one risk that was understated is
19 the development of opioid use disorder.

20 Q. (BY MR. HERMAN:) Okay. What -- what
21 other risks were understated?

22 A. Overdose is, you know, a pretty clear
23 one. And I believe I cite another paper that goes
24 through quite a few other medical conditions that
25 are consequential to prescribed opioid use.

1 Q. Who understated the risk of overdose?

2 MR. ARBITBLIT: Object to form.

3 A. Who understated the risks of
4 overdose?

5 Q. (BY MR. HERMAN:) Yes.

6 A. I'm not sure I --

7 Q. Well, you said the risks of overdose
8 were understated, that that was one of the risks
9 that was understated. So I was just asking who,
10 who understated, if you know?

11 A. I think there certainly is evidence
12 from drug manufacturers, and there may be other
13 companies that also produce material that included
14 information on the supposed safety of these
15 medications that may not have been accurate.

16 Q. Sitting here today, the only one you
17 are aware of, though, is drug manufacturers?

18 A. I am not offering opinions about
19 specific companies' materials. I think there's
20 sufficient evidence that, overall, various
21 companies that sold and distributed opioids
22 understated risks.

23 Q. Well, I -- Professor Keyes, I am sure
24 in your professional life, you want to be pretty
25 precise when you say things like that, that

1 companies, generally -- I'm just asking: Sitting
2 here today, I'm not asking you for a specific. I
3 asked you about a category, manufacturers.

4 Is that the only category you are
5 aware of that understated the risks that you are
6 speaking about?

7 MR. ARBITBLIT: Object to form.

8 A. I am not offering opinions about any
9 specific companies at this time because I haven't
10 evaluated those specific materials.

11 But I believe throughout the material
12 that I have cited in this report, including the IOM
13 report, including several other sources of
14 material, there's sufficient evidence that a broad
15 range of companies that sold opioids understated
16 the risks.

17 Q. (BY MR. HERMAN:) Are you aware of
18 any statement by pharmacists or pharmacies that
19 understated the risks of prescription opioids,
20 sitting here today?

21 MR. ARBITBLIT: Object to form.

22 A. I have not evaluated that specific
23 material, and I am not offering an opinion on that.

24 Q. (BY MR. HERMAN:) And the concern you
25 are expressing in the testimony we have looked at

1 was that doctors relied on what you -- what you
2 believe to be an understatement of the risks of
3 opioids, correct?

4 A. In this specific testimony?

5 Q. That is right.

6 A. I was referring to physicians, yes.

7 Q. And do you have any reason to believe
8 that pharmacists had better information than
9 doctors about the risks and benefits of
10 prescription opioids?

11 MR. ARBITBLIT: Object to form.

12 A. I don't have any -- I haven't
13 evaluated any material that would indicate that
14 pharmacists had different information.

15 Q. (BY MR. HERMAN:) Do you fault
16 pharmacists for filling prescriptions written by
17 licensed doctors for FDA-approved medications that
18 the prescriber intended would be used for
19 legitimate medical purposes?

20 MR. ARBITBLIT: Object to form.
21 Incomplete hypothetical.

22 A. My testimony would be that pharmacies
23 have a responsibility to do -- to do what is
24 required of them in order to dispense safely. And
25 so in terms of what caused the opioid crisis, I

1 would certainly look at all of those distribution
2 channels, including pharmacies.

3 Q. (BY MR. HERMAN:) What's the basis
4 for your statement that pharmacies have a
5 responsibility? Where did you gain that
6 understanding?

7 A. I think it is well-known in terms of
8 kind of opioid policy and epidemiology.

9 Q. What specifically are you pointing to
10 for your assertion that pharmacies have -- as
11 opposed to pharmacists, have an obligation when
12 dispensing prescription medications?

13 MR. ARBITBLIT: Object to form.

14 A. I am pointing to my knowledge of
15 epidemiology and opioid policy.

16 Q. (BY MR. HERMAN:) Well, what
17 specifically are you pointing to other than
18 something that -- like how did you gain that
19 understanding?

20 MR. ARBITBLIT: Objective --
21 objection, vague. Asked and answered.

22 A. I gained understanding of
23 epidemiology and opioid policy through my research
24 and my expertise.

25 Q. (BY MR. HERMAN:) What specific

1 policy are you pointing to?

2 MR. ARBITBLIT: Objection, vague.

3 Q. (BY MR. HERMAN:) Sitting here today,
4 can you point me to any document or law or
5 regulation, any source that you are relying on for
6 that statement that pharmacies, as opposed to
7 pharmacists, have an obligation with regard to
8 dispensing prescription opioids?

9 MR. ARBITBLIT: Objection, vague.

10 A. My general -- this comes from my
11 general knowledge about opioid law, which varies
12 across time and across states. And my general
13 knowledge is that pharmacies and the people who
14 work there have a responsibility to dispense
15 responsibly.

16 Q. (BY MR. HERMAN:) What law
17 specifically?

18 MR. ARBITBLIT: Object to form.

19 A. I think there are various regulations
20 in various states that inform what pharmacies have
21 a responsibility to do in order to dispense
22 appropriately.

23 Q. (BY MR. HERMAN:) Have you ever
24 written anything on the laws or regulations
25 surrounding the practice of pharmacy?

1 A. I am certainly involved in a number
2 of different opioid policy projects that include
3 regulations that would include pharmacies in them.

4 Q. Have you ever written anything
5 about --

6 THE REPORTER: I'm sorry. You
7 garbled. "Have you ever written anything" --

8 Q. (BY MR. HERMAN:) Have you ever
9 written anything evaluating the laws and
10 regulations of a pharmacy in connection with
11 dispensing of prescription opioids?

12 A. I have certainly written a lot about
13 opioid policies, some of which covers pharmacies
14 and some which do not, including information on
15 prescription drug monitoring programs. I have
16 written a number of articles about various
17 prescription drug monitoring programs and how they
18 differ by state. And so I would point to those
19 articles as providing a basis for my expertise.

20 Q. Well, I mean I have read all your
21 articles on opioids, and I don't recall any of them
22 discussing the obligations of a pharmacy or
23 pharmacist when dispensing prescription opioids.

24 MR. ARBITBLIT: Objection. There's
25 no question pending.

1 Q. (BY MR. HERMAN:) Can you point me to
2 a specific article?

3 A. There are two systematic reviews on
4 prescription drug monitoring programs that cover
5 basically all fifty states across the last fifteen
6 years. And so those would be articles that I would
7 point to that would include information and laws
8 that would regulate pharmacies.

9 Q. Do you know if there's any law in
10 Ohio that says a pharmacy, as opposed to the
11 pharmacist, has to check the OARRS system?

12 MR. ARBITBLIT: Object to form.
13 Calls for a legal conclusion.

14 A. Yeah. I don't have expertise on the
15 particulars of the OARRS system and how it -- and I
16 am not offering an opinion how that regulates
17 pharmacies versus pharmacists.

18 Q. (BY MR. HERMAN:) Okay. Are you
19 offering -- the only -- so far, the only obligation
20 I have heard you talk about are prescription drug
21 monitoring programs. Can you think of any others
22 that you have written about?

23 MR. ARBITBLIT: Object to form.

24 A. Yes -- sorry, Don. I cut you off.

25 MR. ARBITBLIT: I said object to

1 form. Misstates the testimony.

2 A. I have written about a number of
3 different opioid laws and policies and more
4 broadly, drug laws and drug policies. That is one
5 of my areas of expertise. So I have written about
6 an extensive array of drug policies.

7 Q. (BY MR. HERMAN:) Okay. Well, going
8 back to PDMPs, do you have an understanding of
9 whether in Ohio, a pharmacist is required to check
10 the OARRS system in all circumstances or every time
11 a prescription opioid is dispensed?

12 MR. ARBITBLIT: Object to form.
13 Calls for a legal conclusion.

14 A. I have a general understanding of the
15 Ohio law, and my understanding is that there's some
16 controversy around the circumstances in which the
17 PDMP is required to be checked, which is why there
18 is a lot of overprescribing.

19 Q. (BY MR. HERMAN:) Do you have an
20 understanding of whether the obligations of when a
21 pharmacist is supposed to check the PDMP have
22 changed over time?

23 A. In Ohio?

24 Q. Yes.

25 A. Yes. My understanding is that there

1 have been some changes to those regulations.

2 Q. Do you have -- are you claiming
3 expertise in the obligations of pharmacists with
4 regard to the OARRS system and their obligations in
5 connection with it?

6 A. My expertise is generally on opioid
7 policy, although I am not offering a specific
8 opinion about pharmacists and the OARRS system.

9 Q. Okay. Are you offering an opinion
10 about pharmacies and the OARRS system?

11 MR. ARBITBLIT: Object to form.

12 A. I'm not offering -- sorry.

13 MR. ARBITBLIT: Objection, vague.

14 Q. (BY MR. HERMAN:) Go ahead.

15 A. I am offering opinions about PDMPs in
16 general, but not on the OARRS system in particular.

17 Q. Are you offering opinions about a
18 pharmacy's connection or obligations in connection
19 with use of the OARRS system?

20 A. I'm not offering an opinion about
21 that.

22 Q. Do you know if pharmacies, as opposed
23 to pharmacists, have the ability to access the
24 OARRS system?

25 A. I guess I don't know what you mean by

1 pharmacies, because they are comprised by people.

2 I mean, pharmacies are buildings.

3 Q. Well, you testified -- excuse me if I
4 am wrong, but I believe you testified earlier you
5 were drawing a distinction and saying that both
6 pharmacies and pharmacists had obligations in
7 connection with dispensing opioids. Did I
8 understand you correctly?

9 A. My testimony was that yes, pharmacies
10 have obligations in terms of their
11 responsibilities.

12 Q. Okay.

13 A. But --

14 Q. Go ahead. I'm sorry. Well, the only
15 one I have heard you mention so far, and we will
16 keep going, but is in connection with PDMP usage.
17 So I am asking you, do pharmacies have obligations
18 to check the OARRS system in Ohio in connection
19 with dispensing prescription opioids?

20 MR. ARBITBLIT: Objection. Calls for
21 a legal conclusion.

22 A. My general understanding of the
23 regulation would indicate that they do. But that
24 is based on my reading of it as an epidemiologist.

25 Q. (BY MR. HERMAN:) And you are

1 qualifying your reading as an epidemiologist
2 because you don't have expertise in interpreting
3 the laws surrounding the practice of pharmacy,
4 correct?

5 MR. ARBITBLIT: Object to form.

6 A. I have expertise in analyzing data
7 and in -- and included in that analysis of data has
8 been developing a pretty strong understanding of
9 opioid policies and how they differ.

10 That being said, I'm not a lawyer.
11 And so I -- you know, my reading of it as an
12 epidemiologist would seem to indicate that
13 pharmacies do have a responsibility.

14 Q. (BY MR. HERMAN:) Okay. Do you
15 know -- again, do you know if pharmacies, as
16 opposed to pharmacists, can access the OARRS
17 system?

18 A. The pharmacists that are in
19 pharmacies can is my understanding.

20 Q. Okay. And do you know whether,
21 again, whether a pharmacist, in connection with
22 every prescription opioid dispensed, is obligated
23 to check the OARRS system?

24 MR. ARBITBLIT: Objection. Asked and
25 answered. Calls for a legal conclusion.

1 A. My understanding is that there is
2 some -- that the regulations in Ohio are -- there's
3 some -- that they are not always obligated to
4 check.

5 Q. (BY MR. HERMAN:) And so we have
6 talked about OARRS. What other specific
7 obligations do you understand a pharmacy to have in
8 connection with the dispensing of prescription
9 opioids?

10 MR. ARBITBLIT: Objection, vague,
11 compound.

12 A. I would say that my understanding is
13 generally about, you know, understanding the
14 warning label and the risks and benefits in order
15 to properly instruct patients on the usage of the
16 medication.

17 Q. (BY MR. HERMAN:) And is that an
18 obligation that belongs to the pharmacy or the
19 pharmacist?

20 A. Given that the pharmacist works in
21 the pharmacy, I would say that both have a
22 responsibility to provide adequate care to patients
23 who attend -- who get their medications at the
24 store.

25 Q. Okay. So the pharmacist, if I am

1 understanding you correctly, has an obligation, as
2 you interpret it, to counsel the patient on the
3 warning label, correct?

4 MR. ARBITBLIT: Objection. Misstates
5 the record.

6 A. Yeah. I would just go back to my
7 testimony is that my understanding generally is
8 that pharmacies have a responsibility to instruct
9 the patient about the proper usage and risks and
10 benefits of the medication.

11 Q. (BY MR. HERMAN:) Okay. And the
12 reason you are saying pharmacies -- I mean I am
13 just trying to get this straight. You are saying
14 that the pharmacists, because they work in the
15 pharmacy and they should do that, you believe that
16 the pharmacy has on obligation?

17 MR. ARBITBLIT: Object to form.

18 A. Yes.

19 Q. (BY MR. HERMAN:) And so the
20 obligation that you are talking about that is for
21 the pharmacy is sort of if the pharmacist doesn't
22 fulfill his obligation, his or her obligation, you
23 think that the pharmacy is responsible?

24 MR. ARBITBLIT: Object to form.

25 Calls for a conclusion.

1 A. I don't -- this is not an opinion
2 that I am offering in terms of the responsibility.
3 I mean, hundreds of thousands of people are dead
4 from an opioid crisis. And I think that, you know,
5 the responsibility of that is enormous in terms of
6 the toll that this epidemic has taken on the
7 population.

8 And so looking at the various ways
9 that this could have been prevented includes a very
10 close look on pharmacies.

11 Q. (BY MR. HERMAN:) Okay. But you
12 don't actually -- I mean -- okay. Have you -- but
13 you have not taken a close look at -- well, let me
14 strike that.

15 I think you just said that you are
16 not offering opinion on the obligations of
17 pharmacies and pharmacists; is that correct?

18 MR. ARBITBLIT: Object to form.

19 A. That is right.

20 Q. (BY MR. HERMAN:) And you don't
21 actually -- well, I will leave it. All right.
22 Strike that.

23 MR. HERMAN: Should we -- I think we
24 have been going about maybe a little over an hour.
25 Should we take a little bit of a break?

1 MR. ARBITBLIT: I think there's about
2 fifty minutes left.

3 A. Sounds good.

4 MR. HERMAN: Okay. Well, why don't
5 we just take a break. I will try to organize
6 myself a little bit.

7 THE VIDEOGRAPHER: Stand by. We are
8 now off the record. The time on the video monitor
9 is 4:15.

10 (Whereupon, a break was had from 4:15
11 p.m. until 4:27 p.m. EDT)

12 THE VIDEOGRAPHER: Stand by. We are
13 now on the record. The time on the video monitor
14 is 4:27.

15 Q. (BY MR. HERMAN:) Professor Keyes, do
16 you know what percentage of current heroin users
17 were misusing opioids, prescription or illicit, ten
18 years ago?

19 A. Of the current heroin users now, what
20 proportion ten years ago were misusing or using
21 prescription opioids, that is the question?

22 Q. Misusing.

23 A. I don't know of an analysis that has
24 been performed on current heroin users.

25 Q. I ask you to turn to Page 54 of your

1 report.

2 (Pause.)

3 Q. (BY MR. HERMAN:) And what I
4 understand, if you look at the bottom of the
5 page -- well, I'm sorry. Let's start with 53. I
6 apologize. And one of the things you do here is
7 you are estimating the number of people with opioid
8 use disorder in Lake and Trumbull County, correct?

9 A. Yes.

10 Q. And at the bottom of Page 53, you
11 acknowledge that estimating the number of people
12 with opioid use disorder is a challenge, given that
13 there's no systematic way to count this population,
14 correct?

15 A. Yes.

16 Q. And so what you did was you took the
17 calculated overdose rate of 0.52 per one hundred
18 persons from the Larney systematic review and then
19 divided that overdose rate into the number of
20 overdoses, correct?

21 Well, that may be -- that may be too
22 simplistic because you made an adjustment for
23 fentanyl. As to prescription, the proportion that
24 you estimate to be prescription opioids, you use
25 the 0.52 per one hundred person-years from the

1 Larney study?

2 A. No. The total number of opioid
3 users, I don't think I include the number of
4 prescription opioid users specifically in this
5 calculation. So I took the total drug overdose
6 deaths and divide it by several different estimates
7 of death rates, one of them being 0.52 per hundred
8 thousand.

9 Q. And the other one being 1.56, which
10 is your adjustment for -- based on multiplying that
11 0.52 by three; is that correct?

12 A. That's correct.

13 Q. And on -- and the Larney study was
14 examining the risk for all overdose deaths,
15 regardless of the drug that caused the overdose,
16 correct?

17 A. All drug poisoning deaths, yes.

18 Q. And so it wasn't limited to deaths
19 caused by prescription opioids or opioids
20 generally?

21 A. That's correct.

22 Q. And on Page 54 at the bottom, you
23 write, "However, the application of the 0.52 per
24 one hundred person-years estimate needs to be
25 adjusted for the increase in death rate that

1 occurred after fentanyl adulteration." Correct?

2 A. Yes.

3 Q. Okay. And the reason for that is
4 because fentanyl is more lethal. If you use the
5 same rate, 0.52, you would overestimate the number
6 of opioid use disorder cases in Lake and Trumbull
7 County, correct?

8 A. That is right.

9 Q. And what you are trying to do is to
10 account for the, as you write here, the increase
11 that occurred after fentanyl adulteration, correct?

12 A. Yes.

13 MR. ARBITBLIT: Object to form.

14 Q. (BY MR. HERMAN:) And you placed the
15 time period when fentanyl adulteration began to
16 occur as 2013, correct?

17 A. Not exactly.

18 Q. You don't say in several places in
19 your report that the adulteration of the heroin
20 supply with illicit fentanyl began to occur in
21 2013?

22 A. I used 2013 as an interruption in the
23 time series from 2011 to 2015 for the change in
24 overdose death rates.

25 Q. Well, other places you used 2013,

1 right, like when you are calculating the role of
2 fentanyl illicit versus illicit played in overdose
3 deaths in your estimate, right? You used an
4 average of all deaths before 2013, and you
5 attribute that to prescription opioids, correct?

6 MR. ARBITBLIT: Object to form.
7 Vague.

8 A. That is a different analysis.

9 Q. (BY MR. HERMAN:) Okay. But I stated
10 your analysis correctly, right? You assume for
11 purposes of calculating overdoses that all
12 fentanyl, all 40.4 T-codes before 2013 were
13 prescription opioids?

14 A. I took an average of the years prior
15 to 2013 to estimate a constant number of fentanyl
16 overdoses that were due to prescriptions. So it is
17 not all. It is the average across those years.

18 Q. Well, average after 2013. But to
19 create that average, you assumed that every death
20 that was coded 40.4 before 2013 was a prescription
21 opioid death, correct?

22 A. The average of those years is an
23 estimate of the number of prescription opioid
24 deaths.

25 Q. Okay.

1 A. I don't ever assume that --

2 Q. You don't think --

3 A. I don't --

4 Q. You don't think your overdose death
5 calculations before 2013 treat all deaths coded as
6 40.4 as prescription opioid related?

7 MR. ARBITBLIT: Object to form.

8 A. I believe I have answered the
9 question. The method is to take an average of
10 those overdose deaths prior to 2013 as an estimate
11 of the number of fentanyl cases per year that are
12 due to prescription opioids. It makes no
13 assumption about the total number of T40.4 deaths.

14 Q. (BY MR. HERMAN:) Well, what about --
15 and we can look at some of these later, but I
16 understand that you apply that average going
17 forward for 2013, '14, '15, you know, all the years
18 that follow 2013. But -- 2013 or later. But for
19 2012, if a death is coded T40, you attribute that
20 death to prescription opioids. You don't do that?

21 MR. ARBITBLIT: Object to form.

22 Q. (BY MR. HERMAN:) I see you shaking
23 your head.

24 A. I think I have explained the
25 methodology, but I will explain it again. You take

1 an average of the deaths per year divided by the
2 number of years, and you use that average as your
3 estimate of the number of cases of prescription
4 opioid deaths. I don't make assumption about all
5 T40.4 cases.

6 Q. Well, in 2009, there was a death that
7 was coded T with a T-code 40.4. Did you attribute
8 that death to prescription opioids, or did you
9 treat it some other way?

10 MR. ARBITBLIT: Object to form.

11 A. Are you looking at the specific
12 spreadsheet? I can walk through the specific
13 spreadsheet. Because I have used those numbers for
14 various calculations. I think there might be some
15 confusion.

16 Q. (BY MR. HERMAN:) We will look at it
17 in a second. I think I understand it, but
18 hopefully we can get on the same page.

19 But with the multiplier, if I could
20 ask you to -- you came up with your multiplier
21 three by looking at the increased overdose deaths
22 from 2011 to 2015, correct?

23 MR. ARBITBLIT: Object to form.

24 Q. (BY MR. HERMAN:) And that --

25 THE REPORTER: I didn't hear an

1 answer.

2 MR. HERMAN: Oh.

3 Q. (BY MR. HERMAN:) Professor --

4 A. Yes.

5 Q. And you would agree with me, or maybe
6 not -- do you agree with me that the rise in
7 fentanyl deaths really began 2013 and later?

8 MR. ARBITBLIT: Object to form.

9 A. There was an increase in 2013
10 nationally.

11 Q. (BY MR. HERMAN:) Okay.

12 A. That is a statement I would agree
13 with.

14 Q. If you use a time period from 2011 to
15 2015 and fentanyl began to play an increasing role
16 in overdoses in 2013, 2014, '15, '16 and it kept
17 going up, the role fentanyl was playing in
18 overdoses, wouldn't your multiplier, by using a
19 period that predates the introduction of fentanyl,
20 underestimate the opioid use disorder cases?

21 MR. ARBITBLIT: Object to form.

22 A. No. And I can explain why.

23 What we did was we weighted the
24 denominator of the multiplier correction for the
25 proportion of deaths for which synthetic opioids or

1 T40.4 was involved. So as the years went on in
2 which there was an increasing number of T40.4
3 deaths contributing to the overall drug poisoning
4 deaths, that is accounted for.

5 That is precisely why we used the
6 methods that we did, was because those T40.4 deaths
7 kept increasing. So that by 2018, 2019 when an
8 increasing portion of the overdose deaths are T40.4
9 deaths, we are using that higher death rate
10 weighted to all of those deaths.

11 Q. (BY MR. HERMAN:) But if your 1.56
12 rate, you multiplied -- you came up with your
13 multiplier three by looking -- you multiplied the
14 Larney number, 0.52, by three. And you came up
15 with that three times multiplier by looking at the
16 increase in deaths from 2011 to 2015, correct?

17 A. Yes.

18 Q. And if you looked at -- did you look
19 at whether if you used a time period from, say,
20 2014 to 2019, that the multiplier should have been
21 higher than three?

22 A. That would have been an inaccurate
23 and flawed method. The reliability of my method is
24 that it relies on a standard and time-tested
25 epidemiological practice of using an interruption

1 in a time series. So to describe more simply,
2 what the interruption is intended to estimate is
3 the amount of change in the probability that you
4 die of a drug overdose, given that fentanyl is
5 involved, not the number of people who are using
6 fentanyl. Right.

7 So if you use 2015 to 2019, you would
8 very well capture the number of people using
9 fentanyl, but that would be the wrong number to
10 use. The right number to use is the interruption
11 in the time series immediately prior and
12 immediately after the change in the contamination
13 of the drug supply.

14 So we use that three times number
15 because it was the interruption in the time series
16 and then weight it, each of the denominators for
17 every single year by the total number of drug
18 overdoses that involved T40.4 in order to exactly
19 not fall into the methodological flaw that you are
20 describing of conflating the number of people who
21 use fentanyl with the probability that you die
22 given that you use.

23 Q. Well, I think if you are using a
24 period to account for the increased lethality of
25 fentanyl that predates fentanyl becoming, you know,

1 becoming being adulterated into the drug supply,
2 you don't agree with me that you would
3 underestimate the lethality and the role fentanyl
4 played in overdose deaths?

5 MR. ARBITBLIT: Object to form.
6 Asked and answered.

7 A. Yeah, I can explain it again. I mean
8 you really do need that pre-fentanyl period so you
9 have a baseline, right. You need to know the
10 probability -- the change in the probability of
11 deaths given that you used fentanyl versus that you
12 didn't use fentanyl. So you need a time period in
13 which the majority of people using drugs weren't
14 using fentanyl, right.

15 And so that -- if you have seen other
16 kinds of interrupted time series models, which,
17 again, are very standard in epidemiology, exactly
18 to estimate these types of parameters, I need to
19 know a single point of change. And so when you
20 have this like sharp interruption in a time series,
21 you wouldn't use the later dates to estimate the
22 change in the risk, because that would, again,
23 conflate the number of users with the lethality of
24 deaths.

25 So the interruption of the time

1 series exactly gets at the quantity that we want to
2 get at, which is not how many people are using
3 fentanyl, but is what is the change in the
4 probability of death, given that you use fentanyl
5 compared that you don't use fentanyl, not how
6 widespread is fentanyl use.

7 Q. (BY MR. HERMAN:) Well, can I ask you
8 to look at Table 2? Actually, let's go to --

9 MR. HERMAN: Jason, can I ask you to
10 pull up Exhibit 13?

11 MR. ACTON: Yes.

12 Q. (BY MR. HERMAN:) This is CVS for
13 you, Professor Keyes, 13. One is -- I believe all
14 the tabs are going to be in there. The way this
15 material, your chart was sent to us was as an Excel
16 spreadsheet, which we will put up on the screen,
17 and then PDFs that followed each tab.

18 MR. HERMAN: Why don't we mark that
19 as Exhibit -- what are we up to? -- Exhibit 19.

20 (Exhibit 19 was marked for
21 identification.)

22 MR. HERMAN: And if we could mark --
23 are all the tabs part of one exhibit? Okay. Well,
24 why don't we mark the PDFs as 19-A, B, C, D, E
25 [sic].

1 (Exhibit 19-A was marked for
2 identification.)

3 (Exhibit 19-B was marked for
4 identification.)

5 (Exhibit 19-C was marked for
6 identification.)

7 (Exhibit 19-D was marked for
8 identification.)

9 Q. (BY MR. HERMAN:) And Dr. Keyes, I
10 don't think -- we sent you the PDFs, but we didn't
11 have a good way to send you the Excel spreadsheet
12 with its separate tabs. So I think -- we will put
13 that on the screen, but I think we can hopefully
14 walk through it together.

15 A. Sure.

16 Q. And -- oh, I have it here. Okay.
17 And the tabs that you and I were discussing earlier
18 is Figure 7 and 14 where we were talking about the
19 averaging of T40.

20 A. Yes.

21 Q. Okay. And just so the record may be
22 a little clearer, T40.1 is heroin, correct?

23 A. Yes.

24 Q. And T40.2 refers to natural or
25 semisynthetic opioids such as oxycodone or

1 hydrocodone?

2 A. Yes.

3 Q. Okay. And T40.3 refers to methadone?

4 A. Yes. Yes, I think it is -- I think
5 the category is something that is a little bit
6 broader than that in terms of what it is called.

7 Q. I thought I took it from your report.
8 But we will -- whatever T40.3 is, it includes
9 methadone?

10 A. It includes methadone.

11 Q. And T40.4 refers to synthetic opioids
12 such as fentanyl, correct?

13 A. Correct.

14 Q. And the issue that you and I, maybe
15 not clearly for the record, we are sort of
16 discussing is that T40 doesn't distinguish between
17 prescription fentanyl and illegal fentanyl, right?

18 A. T40.4.

19 Q. T40.4, yeah.

20 A. That's correct.

21 Q. And it also can include fentanyl
22 analogs like carfentanil, for example, right?

23 A. Yes.

24 Q. Okay. And so what you were trying to
25 do in the overdoses is come up with a calculation

1 of when fentanyl became a problem. More of a
2 problem by your estimation post 2013 was what
3 number that T40.4 dash should be attributed to
4 prescription versus illicit fentanyl, correct?

5 A. That's correct.

6 Q. And the way you came up with that
7 number was, if I understand it correctly, is you
8 took -- I want to get my column right, but
9 Column H, and for every year before 2012 -- and we
10 will just use Trumbull County as an example --
11 where there was a number in Column H, you added
12 those up and you divided it by the number of years
13 for which there was a number, correct?

14 A. My -- do you -- I guess one
15 procedural question. Am I allowed to write on
16 this? Just because I -- it is hard to see and I
17 kind of want to circle things. I am happy to turn
18 it in --

19 Q. I think unlike when we did it last
20 time, this isn't -- the exhibit with you I think is
21 not the official exhibit. Someone should correct
22 me if I am wrong, but if it would be helpful to
23 you, I think you can write on it.

24 A. Yeah. It's just I don't have the
25 column number, so I want to figure out -- when you

1 say Column H, it doesn't say Column H on mine.
2 That is okay. I think I can figure it out. And
3 just based on -- I just wanted to make sure it is
4 okay if I write on this.

5 Q. Yeah. Can you see the one that says
6 T40.2 minus T40.4 minus T40.2 -- and then it says
7 "Deaths that only" --

8 A. Yeah.

9 Q. I think that is what I am referring
10 to as Column H. And that is meant to capture
11 overdose deaths that were only T40.4, correct?

12 A. Correct.

13 Q. And so my understanding is that you
14 before 2012 or before 2013, so 2012 or earlier,
15 when you estimated the number of RX deaths, you
16 added the column that is RX opioids not including
17 synthetics, so the one that was T40.2, T40.3, and
18 you added that to Column H. So everything before
19 2012, you treated everything in -- that was a T40.4
20 death as attributable to an RX opioid death. Is
21 that correct?

22 A. Not exactly -- everything that was a
23 T40.4 death that didn't have an additional
24 contributing cause of an additional T-code. So if
25 it had, for example, T40.4 and T40.1 -- that is

1 heroin and fentanyl, for example -- that was not
2 treated as a prescription fentanyl death.

3 Q. Okay. And that is what you did for
4 the time period before 2012, or 2012 or earlier?
5 And then for 2013 --

6 THE REPORTER: I didn't hear an
7 answer.

8 MR. HERMAN: Oh, I'm sorry.

9 THE REPORTER: Question: And that is
10 what you did the time period before 2012, or 2012
11 or earlier?

12 A. And I said that is right.

13 Q. (BY MR. HERMAN:) And after 2012, or
14 2013 and later, my understanding is what you did
15 was -- let's just use Lake County, I think, because
16 it will be easier. Lake County has NA for 1999 to
17 2005, right? Do you see that?

18 A. That is right. Yes.

19 Q. And so you didn't have a number to
20 use. So my understanding is you took the number in
21 Column H for 2006 to 2012. You added those all up
22 and you divided by the number of years for which
23 you had data to come up with an average, right?

24 A. Yep. Yes.

25 Q. And then you rounded that up.

1 Because I think the number for each of these is 2.,
2 I think, five something and one is 2.7 something.
3 So you rounded that up to three, right?

4 A. Yes.

5 Q. And then carrying that forward, you
6 treated for each year three of the T40.4 overdoses
7 as directly attributable to prescription opioids,
8 correct?

9 A. That is right.

10 Q. And I think there was one year --
11 there was one year where I believe that -- and it
12 is in Lake County where it says, 2013, if you see
13 Column H has zero in it --

14 A. Yes, I see that.

15 Q. And when you go over to Column J,
16 which I understand to be directly attributable to
17 prescription opioids, it looks like you still added
18 three to the nineteen. Was it -- I'm just
19 wondering whether that was an oversight or whether
20 there is a reason why that would occur.

21 A. I would have to go back and look
22 through my calculations to see what I actually did
23 there, because I don't have the calculations on
24 this spreadsheet and I can't see the column
25 headings either.

1 Q. Yeah. Well, if there's zero T40.4
2 deaths in the data, would you agree with me that
3 you shouldn't add three T40.4 deaths to that?

4 A. Not exactly. There's not zero T40.4
5 deaths in the data. That is the estimate of the
6 number of T40.4 deaths that don't have an alternate
7 contributing cause. So there are T40.4 deaths in
8 the data. So to derive an estimate of the number
9 of total T40.4 deaths that are attributable to
10 prescription opioids doesn't necessarily preclude a
11 year in which there are zero T40.4-only deaths from
12 having deaths that were due to prescription
13 fentanyl.

14 So I generally try in my
15 epidemiological practice to keep my rationale and
16 my methods really consistent so that I don't fall
17 into kind of methodological errors like assuming
18 that a year in which there was zero T40.4 deaths
19 only to be no deaths attributable to prescription
20 opioids.

21 But I would have to go back and look
22 at the calculations to know for sure.

23 Q. Okay. So am I understanding you
24 correctly that if, for example, anything listed in
25 Column H was only coded for T40.4, it didn't have

1 potentially a T40.1 code as well?

2 A. Well, it is an estimate of that,
3 because we can't directly estimate the number of
4 T40.4-only deaths from the CDC WONDER. All we can
5 do is estimate the total number of T40.2 plus T40.3
6 plus T40.4 and we subtract out the T40.2 and T40.3
7 to try to get an estimate of how many of those are
8 T40.4 only. But that doesn't preclude all of the
9 T40.4 deaths in that group.

10 Q. But did you exclude T40.1 from those,
11 or is it possible that someone that had -- is it
12 possible that -- let's just stick with 2013 -- that
13 your column that has 19 in it, which is -- includes
14 T40.2, T40.3 and T40.4, could that also include
15 T40.1, or no, you excluded those?

16 MR. ARBITBLIT: Object to form.

17 A. It absolutely does. Because, as I am
18 sure you know, there are -- there's no -- people
19 can be prescribed fentanyl and be using heroin. So
20 you would not want to subtract out heroin users
21 from that group.

22 Q. (BY MR. HERMAN:) Okay. And the only
23 thing you looked at are T-codes related to opioids,
24 correct?

25 MR. ARBITBLIT: Object to form.

1 A. For which --

2 Q. (BY MR. HERMAN:) Well, for all this,
3 this entire chart, right. It is only looking at
4 T40.1, T40.2, T40.3 and T40.4, right?

5 A. This chart only includes those
6 T-codes, yes.

7 Q. And it is possible that these
8 individuals had T-codes for other substances like
9 cocaine?

10 A. I didn't look at that.

11 Q. It is possible they had T-codes
12 for -- well, you didn't look at whether they
13 included T-codes for any nonopioid drugs?

14 A. Yes. I did not look at that, as it
15 was not the purpose of this chart.

16 Q. Okay. And I just had a question
17 about your Figure 13 as well. Where -- I apologize
18 if I missed it in your report, but my understanding
19 is you are applying the Ohio numbers to the Ohio
20 HUD rate and Ohio POUD rate to Lake and Trumbull
21 County to come up with your estimate; is that
22 correct?

23 A. Just so I can get on the same page,
24 we are looking at Figure 13, which is the number of
25 individuals with opioid use disorder that are

1 directly attributable to prescription opioids. And
2 you are looking at the spreadsheet over here. I
3 guess it is not -- 13. -- 13-D is where I derive
4 the numbers that go into Figure 13.

5 And part of that calculation includes
6 the Ohio heroin use disorder and Ohio prescription
7 opioid use disorder rate and their overlap, their
8 estimated overlap.

9 Q. Okay. And so you used the Ohio
10 numbers that you -- and where did you get those
11 rates from?

12 A. Those were from the National Survey
13 on Drug Use and Health.

14 Q. Well, and so are we talking about --
15 let's be clear. Are we talking about the 53.4
16 percent number, or is that the number you are
17 discussing when you are talking about the rate that
18 you got? Or are you talking about --

19 A. That is different.

20 Q. Okay. Which rate -- can you give me
21 a number, just to orient me? Because I think --

22 A. So in Exhibit CVS 13-D --

23 Q. Uh-huh.

24 A. -- on the top box, we have the total
25 number -- so let's just take 2015 as an example.

1 Q. Yep.

2 A. There's the total number of OUD
3 cases, which is estimated using that multiplier
4 method that we went through.

5 Q. Yep.

6 A. And we have the total population
7 size.

8 Q. Uh-huh.

9 A. The methodology used to estimate what
10 proportion of those OUD cases are directly
11 attributable to prescription opioids involves
12 looking at the percentage of heroin use disorder
13 and prescription opioid use disorder and their
14 overlap, and using those percentages to derive the
15 number that are directly attributable to
16 prescription opioids.

17 Q. Okay. And you are using the Ohio
18 rate, which I think you told me you got from the
19 National Drug Use Survey?

20 A. National Survey on Drug Use and
21 Health.

22 Q. Okay. All right.

23 MR. HERMAN: Well, if you give me
24 five minutes, I may be done.

25 THE VIDEOGRAPHER: Stand by. We are

1 now off the record. The time on the video monitor
2 is 5:01.

3 (Off-the-record discussion.)

4 (Whereupon, a break was had from 5:01
5 p.m. until 5:11 p.m. EDT)

6 THE VIDEOGRAPHER: We are now on the
7 record. The time on the video monitor is 5:11.

8 Q. (BY MR. HERMAN:) Dr. Keyes, can I
9 ask you to go to Page 24 of your report. I just
10 want to touch on something we touched on earlier,
11 but I didn't have the articles handy.

12 On Page 24 of your report, under the
13 first bold heading, do you see where you say,
14 "Available estimates indicate that ninety percent
15 of patients prescribed opioids after surgery have
16 unused medications, most of which are not disposed
17 of or stored properly -- or stored safely"?

18 A. Stored safely.

19 Q. Okay. And if I could ask you to take
20 out -- this was a study I mentioned earlier -- what
21 is CVS 7-17 for -- in your folder. And this is
22 going to be Exhibit 20 for the deposition.

23 (Exhibit 20 was marked for
24 identification.)

25 Q. (BY MR. HERMAN:) Do you have that,

1 Professor Keyes?

2 A. I do. I do.

3 Q. And this is an article that I
4 referenced earlier titled "Unused Opioid Analgesics
5 and Drug Disposal Following Outpatient Dental
6 Surgery: A Randomized Controlled Study [sic]." Do
7 you see that?

8 A. I do.

9 Q. And this is one of the articles you
10 cite in support of your statement that available
11 estimates indicate that ninety percent of patients
12 prescribed opioids after surgery have unused
13 medication, correct?

14 A. Yes.

15 Q. Page 79, the reference is 79 in your
16 report.

17 A. Yes.

18 Q. And if I could ask you to go to Page
19 2 and the first column, the fourth paragraph down.
20 And do you see where it says, "The primary aim of
21 this study was to describe patterns of opioid
22 prescribing and consumption after dental surgery
23 with a specific focus on measuring the quantity of
24 opioids left unused"?

25 A. Yes, I see that.

1 Q. Okay. And if you go to the next page
2 under the heading 3.1, do you see that in this
3 study, they found that most patients, ninety-four
4 percent, received a prescription for an opioid
5 containing analgesic after tooth extraction?

6 A. I do.

7 Q. So at least in this study,
8 ninety-four percent of patients got a prescription
9 opioid -- prescription written for them after a
10 tooth extraction, correct?

11 A. Yes.

12 Q. And if you go to Page 5, Section 4.1,
13 and do you see where it says, "We found that
14 fifty-four percent of opioid pills prescribed to a
15 patient in this study (excluding those with dry
16 socket) were left unused after surgery. Based on
17 the national volume of surgical tooth extractions
18 and literature on dental practitioners' prescribing
19 practices, our results suggest that more than a
20 hundred million opioid analgesic pills are left
21 unused following surgical tooth extraction in the
22 United States every year."

23 A. Yes. I see that.

24 Q. Okay. So earlier I asked if there
25 was an article that suggested that there were more

1 than a hundred million opioid analgesic pills that
2 are left unused following surgical tooth
3 extractions in the United States each year. Is
4 that what this article says?

5 A. Well, they don't calculate that -- I
6 mean they haven't done a primary data analysis on
7 that one hundred million opioid analgesic pills.
8 They are extrapolating about a hundred million
9 opioid analgesic pills if you assume that
10 fifty-four percent of opioid pills in this sample
11 that were unused can be mapped accurately onto the
12 national volume of tooth extractions.

13 Q. Do you take issue with their analysis
14 not involving a primary data review?

15 A. I think that their analysis is fine.
16 What I would be cautious about is interpreting this
17 study as showing that there's a hundred million
18 opioid analgesic pills unused, because that is not
19 what they are purporting to do.

20 Q. Okay. Well, they do say that their
21 results suggest that there are a hundred million
22 unused opioid pills following tooth extractions in
23 the United States per year, right?

24 MR. ARBITBLIT: Object to form.

25 A. The study states, "Our result

1 suggests that more than one hundred million opioid
2 analgesic pills are left unused following tooth
3 extractions in the United States." That is what
4 the text says.

5 Q. (BY MR. HERMAN:) And I guess I am
6 not understanding. What issue are you taking with
7 that extrapolation?

8 A. I don't take an issue with their
9 extrapolation. I would not conclude from this that
10 this conclusively demonstrates that there are one
11 hundred million unused pills. That is an estimate
12 from this study.

13 Q. Okay.

14 A. So if you say studies have shown that
15 there's a hundred million unused pills, that is not
16 what the study shows nor is it -- it is not
17 claiming to show that.

18 Q. I think I understand. They are
19 making an estimate that is extrapolation. But to
20 actually know whether there were really a hundred
21 million pills left over, you would have to do
22 additional primary data analysis; is that right?

23 MR. ARBITBLIT: Object to form.

24 A. Additional analyses would need to be
25 done in order to conclude that this -- you would

1 have to do a study to -- that would provide
2 rigorous analysis to conclude that there are a
3 hundred million unused pills. That is not what
4 this study was trying to show.

5 Q. (BY MR. HERMAN:) Okay. But -- all
6 right. And if you go down, though, the next
7 paragraph, it is, "these results are consistent
8 with prior research regarding opioid use among
9 post-surgical patients. Bates surveyed patients
10 following urological surgery and found that
11 forty-two percent of prescribed opioids remained
12 unused two to four weeks after the procedure.
13 Harris found that fifty-nine percent of opioids
14 prescribed following outpatient dermatological
15 surgery were left unused, and Rogers identified
16 that sixty-six percent of opioids were unused among
17 patients following outpatient orthopedic surgery."

18 And so it is discussing a number of
19 studies that have found that prescription opioids
20 are left over from prescriptions doctors write to
21 their patients, correct?

22 MR. ARBITBLIT: Object to form.

23 A. These studies show that there's a
24 large proportion of opioids that are unused.

25 Q. (BY MR. HERMAN:) And if you go to

1 the conclusion -- and this is, I believe, a study
2 that was written in 2016, correct?

3 A. The data are from a randomized
4 control trial that was conducted in 2015.

5 Q. And this study was published in 2016?

6 A. It was published in 2016.

7 Q. And dentists -- and if you go to the
8 Conclusion, it says, "Dentists and oral surgeons
9 could substantially reduce the amount of
10 prescription opioids available for diversion by
11 reducing the quantity of opioids prescribed
12 following these procedures. Recently-published
13 recommendations in the dental literature highlight
14 this opportunity," right?

15 A. Yes, that is what that says.

16 Q. And would you agree with me that the
17 studies that you cite on unused prescription
18 opioids -- there are, I believe, three of them
19 here -- that they are directed to trying to change
20 prescriber behavior and the amount of opioids that
21 they prescribe to patients following various
22 surgical procedures?

23 A. No. The next sentence of this paper
24 says, "The availability of a pharmacy-based drug
25 disposal program with a financial incentive to

1 return unused opioid analgesics is associated with
2 a lower rate of patients indicating that they
3 planned to keep their leftover opioid pills."

4 So I think, at least with this paper,
5 they are suggesting multiple points of intervention
6 to reduce opioid -- unused opioid pills, some at
7 the pharmacy level and some at the provider level.

8 Q. So they are suggesting, one, that
9 prescribers reduce the number of prescription
10 opioids that they prescribe for dental surgery,
11 correct?

12 A. That is one intervention that is
13 recommended.

14 Q. And two, they are suggesting that
15 there are potentially pharmacy-based drug disposal
16 programs with a financial incentive to get the
17 patients to bring back unused prescription opioids,
18 correct?

19 A. That is another intervention that is
20 recommended in this paper.

21 Q. And do you agree that the other two
22 studies that you cite about unused prescription
23 opioids following surgical procedures are directed
24 at changing prescriber behavior in the
25 prescriptions that they write?

1 MR. ARBITBLIT: Object to form.

2 A. I would not agree with that without
3 reviewing the articles.

4 Q. (BY MR. HERMAN:) Well, do you recall
5 that one of them discusses finding the ideal
6 number, and it estimates a number that would
7 satisfy eighty percent of the patient's pain needs?

8 MR. ARBITBLIT: Object to form.

9 A. I would need to look at the article.

10 Q. (BY MR. HERMAN:) Why don't we do
11 that.

12 MR. HERMAN: If I could ask you,
13 Jason, to pull up seven --

14 Q. (BY MR. HERMAN:) Professor Keyes, if
15 you could get out 7-16, 7-16.

16 (Exhibit 21 was marked for
17 identification.)

18 MR. HERMAN: And this will be Exhibit
19 21.

20 Q. (BY MR. HERMAN:) Dr. Keyes, do you
21 have that?

22 A. I do.

23 Q. And this is called -- this article is
24 titled "Wide Variation in Excessive Dosage of
25 Opiate Prescriptions for Common General Surgical

1 Procedures," correct?

2 A. Yes.

3 Q. Okay. And this is an article that
4 was published in 2017, correct?

5 A. Yes.

6 Q. Okay. It is one you cite in your
7 report?

8 A. I do.

9 Q. Okay. And can I get you to look at
10 the first page, 709, second column, the last
11 paragraph. Do you see where it says, "Providers
12 both have societal imperative to avoid
13 overprescribing and an obligation to ensure their
14 patient's post-operative pain is addressed"? Do
15 you see that text?

16 A. I do.

17 Q. And does that refresh your
18 recollection that this paper, and we can go through
19 more of it, is trying to address overprescribing by
20 doctors balanced against the need to address
21 post-operative pain?

22 A. That is not my read of the purpose of
23 the paper. In the background section of the
24 abstract, they talk about diversion as a major
25 contributor to mortality. And while the

1 introduction focuses -- one paragraph of the
2 introduction focuses on providers, other paragraphs
3 focus on other --

4 Q. And what they are trying to do is to
5 get prescribers to write less opioid prescriptions
6 so there's less opportunity for pills left over
7 after surgery to be diverted, correct?

8 A. That is not what their conclusion is
9 or their objective as stated.

10 Q. That is not your understanding? All
11 right. Well, let's keep going.

12 So under Methods, they "evaluated the
13 five most common outpatient general surgery
14 procedures performed at our academic medical
15 facility in 2019. These were partial mastectomies,
16 partial mastectomies sentinel lymph node biopsy,
17 laparoscopic" -- I can't pronounce that word, but
18 "cholecystectomy, laparoscopic inguinal hernia
19 repair and open inguinal hernia repair," right?

20 A. Yes.

21 Q. And if you look at the next column
22 over up at the very top, they found that in 2015
23 for those five procedures, 581 (90.5 percent)
24 patients were prescribed an opioid, right?

25 A. Correct.

1 Q. And if you go down to the last
2 paragraph, they obtained phone survey data on
3 prescription opioid pills actually taken for a
4 hundred and twenty-seven of those patients. Is
5 that right?

6 A. That's right.

7 Q. And what they found was that a total
8 of three thousand five hundred and forty-five pills
9 were prescribed to those one hundred twenty-seven
10 patients and that two thousand five hundred and
11 twenty-seven, 71.3 percent, excess pills were
12 prescribed, right?

13 A. Uh --

14 Q. If you look at the last sentence on
15 Page 7 tab.

16 A. I see. I see. Two thousand five
17 hundred and twenty-seven excess pills.

18 Q. And then if you go to Page 711, do
19 you see in the second paragraph it says, "We
20 calculate an ideal number of pills to prescribe for
21 each operation by determining the number of pills
22 that would satisfy approximately eighty percent of
23 patients' post-operative opioid use"?

24 Do you see that?

25 A. I do.

1 MR. ARBITBLIT: I think we are out of
2 time.

3 MR. HERMAN: Are we out of time?

4 MR. ARBITBLIT: Five hours, we are
5 done.

6 MR. HERMAN: Okay.

7 THE VIDEOGRAPHER: Off the record?

8 MR. HERMAN: Thank you.

9 THE VIDEOGRAPHER: Stand by. You are
10 now off the record. The time on the video monitor
11 is 5:28.

12

13

14 (Deposition concluded at 5:28 p.m. EDT)

15

16 FURTHER THE DEPONENT SAITH NOT

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C E R T I F I C A T E

STATE OF ALABAMA
JEFFERSON COUNTY

I hereby certify that the above and foregoing deposition was taken down by me in stenotypy, and the questions and answers thereto were reduced to typewriting under my supervision, and that the foregoing represents a true and correct transcript of the deposition given by said witness upon said hearing, to the best of my ability.

I further certify that I am neither of counsel nor of kin to the parties to the action, nor am I in anywise interested in the result of said cause.



/s/ LAURA H. NICHOLS

Commissioner-Notary Public, State of AL

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Transcript Certified on 6/3/2021

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

June 4, 2021

To: MR. ARBITBLIT

Case Name: National Prescription Opiate Litigation - Track 3 v.

Veritext Reference Number: 4621640

Witness: Katherine Keyes , Ph.D. Deposition Date: 6/3/2021

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4621640

CASE NAME: National Prescription Opiate Litigation - Track 3 v.

DATE OF DEPOSITION: 6/3/2021

WITNESS' NAME: Katherine Keyes , Ph.D.

In accordance with the Rules of Civil
Procedure, I have read the entire transcript of
my testimony or it has been read to me.

I have made no changes to the testimony
as transcribed by the court reporter.

Date Katherine Keyes , Ph.D.

Sworn to and subscribed before me, a
Notary Public in and for the State and County,
the referenced witness did personally appear
and acknowledge that:

They have read the transcript;

They signed the foregoing Sworn
Statement; and

Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal

this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4621640

CASE NAME: National Prescription Opiate Litigation - Track 3 v.

DATE OF DEPOSITION: 6/3/2021

WITNESS' NAME: Katherine Keyes , Ph.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

Katherine Keyes , Ph.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;

They have listed all of their corrections in the appended Errata Sheet;

They signed the foregoing Sworn Statement; and

Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 4621640

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_____ Katherine Keyes , Ph.D.

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____

DAY OF _____, 20____ .

Notary Public

Commission Expiration Date

[& - 2021]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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